

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ALLYN TURNOFSKY, Individually and
On Behalf of All Others Similarly Situated,

Plaintiff,

v.

ELECTROCORE, INC., FRANCIS R.
AMATO, GLENN S. VRANIAK, BRIAN
POSNER, CARRIE S. COX, MICHAEL G.
ATIEH, JOSEPH P. ERRICO, NICHOLAS
COLUCCI, THOMAS J. ERRICO,
TREVOR J. MOODY, MICHAEL W.
ROSS, DAVID M. RUBIN, JAMES L.L.
TULLIS, STEPHEN L. ONDRA, CORE
VENTURES II, LLC, CORE VENTURES
IV, LLC, EVERCORE GROUP L.L.C.,
CANTOR FITZGERALD & CO., JMP
SECURITIES LLC, and BTIG, LLC,

Defendants.

Civil Action: 3:19-cv-18400-AET-TJB

JURY TRIAL DEMANDED

**AMENDED CLASS ACTION COMPLAINT
FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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Court-appointed Lead Plaintiff Carole Tibbs (“Tibbs” or “Lead Plaintiff”) brings this action on behalf of herself and all other persons or entities that: (i) purchased or otherwise acquired electroCore, Inc. (“electroCore” or the “Company”) common stock pursuant and/or traceable to the registration statement and prospectus (collectively with all amendments, the “Registration Statement”) issued in connection with the Company’s June 2018 initial public offering (“IPO” or the “Offering”); and/or (ii) purchased or otherwise acquired electroCore securities between June 22, 2018 and September 25, 2019, inclusive (the “Class Period”), subject to certain exclusions as described in ¶ 42 below (the “Class”). The claims asserted herein arise under (i) Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 (the “Securities Act”), and (ii) Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and United States Securities and Exchange Commission (“SEC”) Rule 10b-5 promulgated thereunder.

Lead Plaintiff’s allegations are based upon personal knowledge as to herself and her own acts, and information and belief as to all other matters. Lead Plaintiff’s information and belief is based upon, *inter alia*, the investigation conducted by and through her counsel, which included, among other things, a review and analysis of: (i) regulatory filings made by electroCore with the SEC; (ii) press releases, news articles, and other public statements issued by or concerning electroCore and the Individual Defendants (defined below); (iii) transcripts of investor calls with electroCore senior management; (iv) analysts’ reports and advisories about the Company; (v) interviews with former employees of the Company; and (vi) other publicly available information. Counsel’s investigation into the matters alleged herein is continuing, and many relevant facts are known only to, or are exclusively within the custody or control of, Defendants (defined below). Lead Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. **INTRODUCTION**

1. electroCore is a bioelectronic medicine company with a non-invasive vagus nerve stimulation (“VNS”) therapy. Its lead product, gammaCore, is used for the acute treatment of pain associated with migraine and episodic cluster headache in adults. gammaCore devices are held alongside the patient’s neck and are intended to lessen headache pain by providing electrical stimulation to the vagus nerve.

2. In June 2018, the Company went public, selling 5.98 million shares of common stock at a price of \$15.00 per share. The Company received net proceeds of approximately \$77.7 million from the Offering. The proceeds from the IPO were purportedly to be used to commercialize gammaCore products, expand the Company’s clinical program into additional indications in headache and rheumatology, build its specialty distribution channel for the anticipated launch of gammaCore Sapphire, and for working capital and other corporate purposes.

3. As detailed herein, the Registration Statement was false and misleading and omitted to state material adverse facts. Among other things, the Registration Statement concealed that electroCore was facing increasing competition and pricing pressure; gammaCore was not enjoying advantages over other treatments and in fact was not even considered a primary treatment; the Company was struggling with physician adoption of the treatment and insurance coverage for gammaCore leading to increasing cash outlays in the form of product discounts, long-term use of voucher programs, and additional sales personnel; all resulting in unsustainable cash burn and an inability to increase revenues.

4. Lead Plaintiff asserts claims arising out of the false and misleading Registration Statement under Sections 11, 12(a)(2), and 15 of the Securities Act against electroCore, certain of its officers and directors, investment funds owned and controlled by certain of these officers and

directors, and the underwriters of the IPO (collectively, the “Securities Act Defendants”). These Securities Act claims expressly exclude any allegations of scienter.

5. Lead Plaintiff also asserts claims arising under Sections 10(b) and 20(a) of the Exchange Act against the Exchange Act Defendants (defined below). As alleged herein, throughout the Class Period, the Exchange Act Defendants made materially false and/or misleading statements, and/or failed to disclose material facts, including that: (i) gammaCore did not enjoy any competitive advantages over other treatments for episodic cluster headaches (“eCH”) and migraines, and in fact was facing increasing competition from similar medical devices that had already been approved for treatment, and a new category of drugs which was specifically designed for migraine prevention; (ii) electroCore was having a multitude of issues in obtaining insurance coverage, but failed to disclose any of them; (iii) despite the Company’s attempts to promote gammaCore as both a durable medical device and a pharmacy benefit, physicians were reticent to prescribe gammaCore as reimbursement was hard to obtain; and (iv) electroCore was dependent on a voucher program to grow sales, but the voucher program was failing to increase revenues and was in fact increasing losses.

6. On May 14, 2019, the Company announced first quarter 2019 financial results that fell short of investors’ expectations, reporting \$410,000 net sales and an operating loss of \$14.2 million, and revealing certain restraints on its agreements with insurance companies limiting reimbursement for gammaCore. On this news, the Company’s share price fell \$1.58, nearly 30%, to close at \$3.75 per share on May 15, 2019, on unusually heavy trading volume.

7. Just two weeks later, on May 29, 2019, the Company announced a drastic restructuring and cost reduction plan. On this news, electroCore’s share price fell \$0.11, or over

5%, to close at \$1.95 per share on May 30, 2019, and continued to drop over the next two trading days, closing at \$1.65 per share on June 3, 2019.

8. On August 13, 2019, electroCore announced a restructuring charge of \$850,000 in connection with the restructuring plan, expected quarterly cash burn exceeding \$7 million, and continuing restrictions on coverage reimbursement. On this news, the Company share price dropped over 10% from a closing price on August 13, 2019 of \$1.56 to a closing price of \$1.39 per share on August 14, 2019.

9. Finally, on September 25, 2019, the Company revealed that the U.S. Food and Drug Administration (the “FDA”) had requested more information and analysis of clinical data for electroCore’s 510(k) submission, which sought an expanded indication for the use of gammaCore. On this news, the Company’s share price fell \$0.79, over 23%, to close at \$2.57 per share on September 25, 2019, on unusually heavy trading volume.

10. By the commencement of this action, electroCore stock was trading as low as \$1.25 per share, a nearly 92% decline from the \$15.00 per share IPO price.

II. JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to (i) Sections 11, 12(a)(2), and 15 of the Securities Act (15 U.S.C. §§ 77k, 77l(a)(2), and 77o), and (ii) Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

13. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), Section 22 of the Securities Act (15 U.S.C. § 77v), and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). The Company's principal executive offices are located within this District.

14. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

A. Lead Plaintiff

15. Lead Plaintiff Tibbs, as set forth in her previously-filed certification (ECF No. 6-4) and incorporated by reference herein, purchased electroCore common stock directly in the IPO and pursuant and/or traceable to the Registration Statement and during the Class Period at artificially inflated prices and was damaged as a result of the federal securities law violations and false and/or misleading statements and material omissions alleged herein.

B. Defendants

16. Defendant electroCore is incorporated under the laws of the state of Delaware with its principal place of business located in Basking Ridge, New Jersey. The Company trades on the NASDAQ under the ticker symbol "ECOR."

17. Defendant Francis R. Amato ("Amato") served as the Company's Chief Executive Officer ("CEO") and member of the Board of Directors (the "Board") from July 2016 until September 30, 2019. Amato served as the Company's Chief Operating Officer from July 2012 through July 2016. According to the Registration Statement, at the time of the IPO, Amato beneficially owned 1.5% of the total common stock of the Company. As of March 15, 2019, Amato beneficially owned 1.87% of the Company's common stock. Amato signed the Company's

Registration Statement and electroCore's Form 10-K for the year ended December 31, 2018 (the "2018 Form 10-K").

18. Defendant Glenn S. Vraniak ("Vraniak") served as the Company's Chief Financial Officer ("CFO") from August 2016 until April 1, 2019. Vraniak signed the Company's Registration Statement and electroCore's 2018 Form 10-K.

19. Defendant Brian Posner ("Posner") has served as electroCore's CFO since April 1, 2019.

20. Defendant Joseph P. Errico ("J. Errico") served as the Company's Chief Science and Strategy Officer from July 2016 until May 31, 2019. J. Errico previously served as electroCore's CEO from January 2010 to July 2016. He co-founded electroCore with defendant Thomas J. Errico ("T. Errico") and non-party Peter S. Staats ("Staats"), has served as a member of the Board since 2005, and as Chairman of the Board from March 2013 until June 2018. According to the Registration Statement, at the time of the IPO, J. Errico beneficially owned 53.8% of the Company's common stock. J. Errico also serves as a Managing Director of defendants Core Ventures II, LLC ("CV II") and Core Ventures IV, LLC ("CV IV"), which in total owned 39.5% of the Company's common stock at the time of the IPO. As of March 15, 2019, J. Errico beneficially owned 39.72% of the outstanding shares of the Company. J. Errico signed or authorized the signing of the Company's Registration Statement. J. Errico also signed electroCore's 2018 Form 10-K.

21. Defendant Thomas J. Errico ("T. Errico") co-founded electroCore with J. Errico and Staats. T. Errico has served as a member of the Board since 2005. During the Class Period, T. Errico served as a member of the Board's Compensation Committee. According to the Registration Statement, at the time of the IPO, T. Errico beneficially owned 52.5% of the

Company's common stock. T. Errico also serves as a Managing Director of defendants CV II and CV IV which in total owned 39.5% of the Company's common stock at the time of the IPO. As of March 15, 2019, T. Errico beneficially owned 38.41% of the outstanding shares of the Company. T. Errico signed or authorized the signing of the Company's Registration Statement. T. Errico also signed electroCore's 2018 Form 10-K.

22. Defendant Carrie S. Cox ("Cox") served as a director and Chairman of electroCore's Board from the time of the IPO until April 1, 2020. During the Class Period, Cox served on the Board's Audit Committee. Cox was identified in the Registration Statement with her consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Cox also signed the Company's 2018 Form 10-K.

23. Defendant Michael G. Atieh ("Atieh") has served as a director of electroCore since the time of the IPO in June 2018. During the Class Period, Atieh served as the Chairman of the Board's Audit Committee. Atieh was identified in the Registration Statement with his consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Atieh also signed the Company's 2018 Form 10-K.

24. Defendant Nicholas Colucci ("Colucci") served as a director of electroCore from August 2017 until June 2020. During the Class Period, Colucci served as Chairman of the Board's Compensation Committee. Colucci signed the Company's Registration Statement and electroCore's 2018 Form 10-K.

25. Defendant Trevor J. Moody ("Moody") has served as a director of electroCore since March 2013. During the Class Period, Moody served as a member of the Board's Compensation Committee. Moody signed the Company's Registration Statement and electroCore's 2018 Form 10-K.

26. Defendant Stephen L. Ondra (“Ondra”) has served as a director of electroCore since the time of the IPO in June 2018. Ondra was identified in the Registration Statement with his consent as an individual who would assume service as a director of the Company upon the effectiveness of the Registration Statement. Ondra also signed the Company’s 2018 Form 10-K.

27. Defendant Michael W. Ross (“Ross”) served as a director of the Company from March 2018 until the completion of the IPO. Ross signed or authorized the signing of the Company’s Registration Statement.

28. Defendant David M. Rubin (“Rubin”) served as a director of the Company from March 2013 until the completion of the IPO. Rubin was designated as a director by stockholder Merck Global Health Innovation Fund, which owned 13.2% of the Company’s common stock at the time of the IPO. Rubin signed or authorized the signing of the Company’s Registration Statement.

29. Defendant James L.L. Tullis (“Tullis”) served as a director of the Company from July 2014 until June 2020. During the Class Period, Tullis served on the Board’s Audit Committee. According to the Registration Statement, at the time of the IPO, Tullis beneficially owned 1.1% of the total common stock of the Company. Tullis signed or authorized the signing of the Company’s Registration Statement. Tullis also signed electroCore’s 2018 Form 10-K.

30. Defendant CV II is a private equity investment firm based in Short Hills, New Jersey and is owned and controlled by defendants J. Errico and T. Errico. Immediately prior to the Offering, CV II owned 33.4% of the Company, and after the IPO, owned 26.7%.

31. Defendant CV IV is a private equity investment firm based in Short Hills, New Jersey and is owned and controlled by defendants J. Errico and T. Errico. Immediately prior to the Offering, CV IV owned 6.1% of the Company, and after the IPO, owned 4.9%.

32. Defendant Evercore Group L.L.C. (“Evercore”) served as an underwriter and joint bookrunner in connection with electroCore’s IPO. In the IPO, Evercore agreed to purchase 2,158,000 shares of the Company’s common stock, exclusive of any over-allotment option.

33. Defendant Cantor Fitzgerald & Co. (“Cantor Fitzgerald”) served as an underwriter and joint bookrunner in connection with electroCore’s IPO. In the IPO, Cantor Fitzgerald agreed to purchase 1,430,000 shares of the Company’s common stock, exclusive of any over-allotment option.

34. Defendant JMP Securities LLC (“JMP”) served as an underwriter and joint bookrunner in connection with electroCore’s IPO. In the IPO, JMP agreed to purchase 1,040,000 shares of the Company’s common stock, exclusive of any over-allotment option.

35. Defendant BTIG, LLC (“BTIG”) served as an underwriter and lead manager in connection with electroCore’s IPO. In the IPO, BTIG agreed to purchase 572,000 shares of the Company’s common stock, exclusive of any over-allotment option.

36. Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are sometimes referred to herein collectively, as the “Individual Defendants.”

37. CV II and CV IV are sometimes referred to herein as the “CV Defendants.”

38. Evercore, Cantor Fitzgerald, JMP, and BTIG are sometimes referred to herein collectively, as the “Underwriter Defendants.”

39. electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, the CV Defendants, and the Underwriter Defendants are sometimes referred to herein collectively, as the “Securities Act Defendants.”

40. electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis are sometimes referred to herein collectively, as the “Exchange Act Defendants.”

41. electroCore, the Individual Defendants, the CV Defendants, and the Underwriter Defendants are referred to collectively herein as “Defendants.”

IV. CLASS ACTION ALLEGATIONS

42. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons or entities that:

(i) purchased or otherwise acquired electroCore common stock pursuant and/or traceable to the Registration Statement issued in connection with the Company’s June 2018 IPO; and/or
(ii) purchased or otherwise acquired electroCore securities between June 22, 2018 and September 25, 2019, inclusive (the “Class Period”), and were damaged upon the revelation of the alleged corrective disclosures. Excluded are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns and any entity in which Defendants have or had a controlling interest.

43. Class members are so numerous that joinder of all members is impracticable. Throughout the Class Period, electroCore securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Lead Plaintiff at this time and can be ascertained only through appropriate discovery, Lead Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other Class members may be identified from records maintained by electroCore or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

44. Lead Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

45. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Lead Plaintiff has no interests antagonistic to or in conflict with those of the Class.

46. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether the Registration Statement contained any material misrepresentations or omissions;
- b. whether Defendants have a viable good faith defense to the strict liability imposed by Section 11 of the Securities Act;
- c. whether Defendants can establish negative causation as a defense to or as a reduction of the strict liability otherwise imposed by Section 11 of the Securities Act;
- d. whether the Individual Defendants and/or the CV Defendants were control persons of electroCore for the purposes of Section 15 of the Securities Act and Section 20(a) of the Exchange Act;
- e. whether the statements made by the Exchange Act Defendants to the investing public during the Class Period misrepresented material facts about the business, operations, and management of electroCore, or omitted facts necessary to make the statements not misleading;
- f. whether the Exchange Act Defendants caused electroCore to issue false and misleading financial statements during the Class Period;
- g. whether the Exchange Act Defendants acted knowingly or recklessly in issuing false and misleading misrepresentations or omissions;
- h. whether the federal securities laws were violated by Defendants' acts as alleged herein;

- i. whether the prices of electroCore securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- j. whether the members of the Class have sustained damages with respect to their Exchange Act claims and, if so, what is the proper measure of damages.

47. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

V. BACKGROUND AND NATURE OF THE WRONGDOING

A. The Company and Its Business

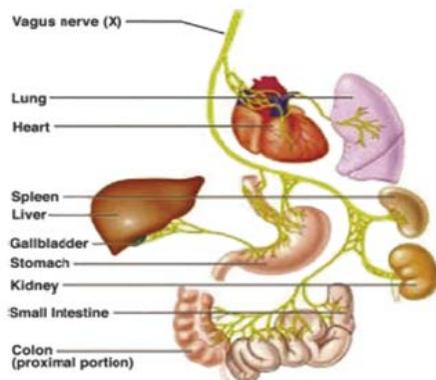
48. electroCore was founded in 2005 as electroCore, LLC by defendant T. Errico, his nephew, defendant J. Errico, non-party Charles Theofilos, and non-party Staats. The Company is “a commercial-stage bioelectronic medicine company with a platform non-invasive vagus nerve stimulation therapy initially focused on neurology and rheumatology.”

49. The Company was at all times extremely small, with only 64 employees at the time of the IPO, increasing to 91 full-time employees as of March 1, 2019. As of March 1, 2020, electroCore had 51 full-time employees.

50. electroCore’s flagship therapy product is gammaCore, a “prescription-only vagus nerve stimulation, or VNS therapy administered in discrete doses using a proprietary” handheld delivery system. More specifically, the gammaCore device stimulates the vagus nerve, the longest cranial nerve carrying signals from the digestive system to the brain, with “high-frequency burst waveform” (*i.e.*, electrical currents) which purportedly “has a measurable pharmacologic effect

similar to several classes of medications.” According to electroCore, prior to gammaCore, VNS “was only accessible to the most refractory patients, who were willing to endure surgery.”

Figure 1: The distribution of the vagus nerve to multiple organs



51. The original gammaCore product was disposable and dispensed therapy on a 31-day prescription basis. Its successor, gammaCore Sapphire (pictured below), is rechargeable and reloadable, intended for multi-year use and activated on a monthly basis through the input of a unique, prescription-only authorization code, delivered via a radio-frequency identification (“RFID”) card. At the time of electroCore’s IPO, the U.S. commercial launch of gammaCore Sapphire was set to take place during the third quarter of 2018, with the original gammaCore product being phased out.



52. In April 2017, the FDA granted electroCore's *de novo* application, granting clearance for commercial sales of gammaCore for acute treatment of pain associated with eCH in adults. A *de novo* review is a regulatory pathway for products deemed to be low to moderate risk, but without an applicable predicate. gammaCore Sapphire was granted clearance by the FDA through the 510(k) pathway in December 2017.

53. Cluster headaches ("CH") are short extremely painful headaches described by patients and physicians as one of the most painful conditions in medicine. CH mainly affects males between 20 to 50 years of age with an "attack" lasting from fifteen minutes to three hours and the attacks clustering for two to twelve-week periods, followed by a remission period. The suicide rate among CH sufferers is reportedly twenty times the U.S. national average, with the condition being sometimes referred to as the "suicide headache." According to electroCore, in the U.S., CH affects approximately 350,000 people (0.1% to 0.2% of the total population), with only about 225,000 people seeking treatment each year and with a total estimated market for treatment in 2018 of \$400 million. According to electroCore, prior to gammaCore, there was only one other FDA-approved CH treatment, injectable sumatriptan.

54. Given the small market for acute CH patients, it was vital for electroCore to expand into other markets. In January 2018, electroCore received FDA clearance for gammaCore's use for the acute treatment of pain associated with migraine in adults. According to the Company, there are approximately 36 million migraine sufferers in the U.S. with a total addressable market for acute treatment in 2018 of \$3.8 billion.

55. At the time of electroCore's IPO, it was in the process of pursuing additional label expansions for adolescent migraine, headache prevention indications, and the treatment of post-traumatic headache.

Table 1: Our Headache Pipeline

Indication	Preclinical / Pilot Trials	Pivotal Trials	FDA Clearance	Commercial Launch ¹	Key Milestones
Acute Treatment of Episodic Cluster Headache					<ul style="list-style-type: none"> FDA clearance April '17 Commercial registry initiated 3Q '17 Full commercial launch expected 3Q '18
Acute Treatment of Migraine					<ul style="list-style-type: none"> FDA label expansion January '18 Full commercial launch expected 3Q '18
Migraine Prevention					<ul style="list-style-type: none"> Final PREMIUM trial data publication expected 2H '18 2nd pivotal trial initiation expected 2H '18
Migraine in Adolescents					<ul style="list-style-type: none"> Pivotal trial initiation expected 2H '18
Post-Traumatic Headache					<ul style="list-style-type: none"> Initial preclinical studies in progress Pilot trial initiation expected 2H '18

56. However, at the same time electroCore was gaining FDA clearance, several other competitors were also being granted FDA clearance for the same uses and/or entering the market. In fact, the FDA granted marketing approval for one such product as early as December 18, 2013. eNeura, Inc.'s ("eNeura") Cerena Transcranial Magnetic Stimulator (TMS) was the first FDA approved device to relieve pain caused by migraine headaches that are preceded by an aura. eNeura's next iteration of TMS, the SpringTMS, received 510(k) FDA clearance on May 23, 2014. SpringTMS is a prescription-only device that utilizes single-pulse Transcranial Magnetic Stimulation to induce very mild electrical currents that can depolarize neurons in the brain and was the first medical device available to patients in the U.S. for the acute treatment of pain associated with migraine headache with an aura. On September 7, 2017, SpringTMS received 510(k) clearance from the FDA and was the only product in the U.S. indicated both for the acute and prophylactic (*i.e.*, prevention) treatment of migraine headache.

57. On March 12, 2014, the Cefaly Acute Medical Device was the first transcutaneous (passing through the skin) electrical nerve stimulation (TENS) device granted marketing approval by the FDA for use before the onset of a migraine, as a preventive treatment. On September 21,

2017, the FDA released the use of a new Cefaly medical device for the acute treatment of migraine, with or without aura. The Cefaly Acute allows migraine patients to use the device during a migraine attack, making the Cefaly medical technology more than just a preventive measure.

58. Another device, the Scion NeuroStim TNM (thermal vestibular stimulator), which is an in-ear prescription device used to stimulate the vestibular system by applying thermal waveforms through earpieces placed in a patient's ear canal for the treatment of migraine headache, was also in the late stages of approval at the time of the Company's IPO. Its application was sent to the FDA on April 17, 2017, and it received FDA approval on March 26, 2018.

59. In addition to these medical devices that all represented potential competitors, a new category of drugs called calcitonin gene-related peptide ("CGRP") inhibitors either received FDA approval or were close to receiving FDA approval prior to the IPO.

60. For example, erenumab (Aimovig), the first FDA approved CGRP for the prevention of migraine in adults, received FDA approval on May 17, 2018. Prior to FDA approval, Amgen, Inc. (U.S.) ("Amgen") had submitted its Biologics License Application to the FDA on May 18, 2017, which the FDA accepted on July 20, 2017. On January 22, 2018, Novartis International AG (rest of world) ("Novartis") announced that the drug met all primary and secondary endpoints in a unique phase IIIb study in episodic migraine patients who had failed multiple prior preventive treatments. Because several additional CGRP inhibitors would soon also be on the market, Amgen and Novartis priced the drug significantly below market expectations. Some analysts had anticipated the initial pricing to be as high as \$833 per month (\$10,000 per year), but the drug was priced at \$575 per month (\$6,900 per year), and with the "Aimovig Copay Program," a patient's out-of-pocket costs could be as little as \$5 per month.

61. Another drug, fremanezumab (Ajovy), received FDA approval on September 14, 2018, but Teva Pharmaceuticals submitted its Biologics License Application to the FDA on October 17, 2017. On December 18, 2017, the FDA accepted the application for priority review for the prevention of migraine and fast track review for the CH development program.

62. Similarly, galcanezumab (Emgality), which is for the preventative treatment of migraine, received FDA approval on September 27, 2018, but the FDA accepted its Biologics License Application on December 11, 2017.

63. Against the increasing competition for select markets, shortly after receiving the January 2018 acute migraine treatment clearance, on February 13, 2018, electroCore filed with the SEC a confidential draft registration statement on Form S-1, with its IPO officially announced in May of 2018.

B. electroCore's Undisclosed Issues

64. In its Registration Statement and in later public filings, statements, and conference calls, electroCore and the other defendants touted the Company's unique competitive advantages and business strategies that would permit electroCore to gain market share and increase sales of gammaCore. Unbeknownst to investors, at the time those statements were issued, *inter alia*, (i) electroCore was facing increasing competition and pricing pressure; (ii) gammaCore was not enjoying advantages over other treatments and in fact was not even considered a primary treatment; (iii) the Company was struggling with physician adoption of the treatment and insurance coverage for gammaCore leading to increasing cash outlays in the form of product discounts, long-term use of voucher programs, and additional sales personnel; and (v) as a result, electroCore was experiencing unsustainable cash burn and an inability to increase revenues, among other things.

Physicians were not Receptive to Prescribing gammaCore
and the Company Struggled to Obtain Commercial Payor and Insurance Coverage

65. Confidential witness (“CW”) 1 was the Senior Director of Medical Affairs at electroCore from June 2018 to November 2018, and then Vice President (“VP”) of Medical Affairs from November 2018 to June 2019. CW1 was involved in overseeing the medical education provided by electroCore about the Company’s products. CW1 spoke with doctors about trial result publications and provided medical education to the Company’s sales staff.

66. In the Registration Statement and throughout the Class Period, Defendants frequently discussed electroCore’s acceptance by physicians, but according to CW1, after speaking with dozens of doctors during 2018 and 2019, CW1 stated that “[t]he biggest issue [CW1] would hear after [] describing the science of the product is they would say ‘I would like to prescribe this. I wish it was covered by the insurance companies.’” According to CW1, there were concerns about the cost to patients since gammaCore was not covered by insurance, meaning patients would have to pay out of pocket, participate in a payment plan, or use a “voucher program,” where electroCore would allow patients to use the device for free for one month.

67. CW2 served as the Medical Science Liaison at electroCore from October 2017 to June 2019, reporting to the VP of Medical Affairs and conveying the science behind gammaCore to physicians, researchers, prescribers, insurance providers, and any other group that requested information about gammaCore. CW2 covered about one-half of the country and traveled regularly to give clinical presentations about gammaCore and the clinical trials. CW2 gave weekly updates to the VP of Medical Affairs about the groups and people spoken to and relayed any new insights, questions, or concerns raised with CW2.

68. CW2 echoed CW1’s physician findings, stating that pricing was the top concern expressed by physicians and that physicians primarily felt gammaCore would be a good fit for

patients in a lot of pain who wanted to avoid pharmaceutical treatments because of a history of addiction. CW2 added that physicians had concerns with gammaCore's 20% placebo rate.

69. Defendants touted "negotiations . . . with more than a dozen additional insurance plans" in the Registration Statement, 2018 Form 10-K, and in other public statements, and blatantly stated in the Registration Statement that the Company had "agreements in place with commercial payors that [electroCore] believe[s], based on [] estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives[.]"

70. And yet, according to CW1, as of June 2019, electroCore was not included on the formulary of any insurance company, explaining that a formulary is the list of drugs and services covered by an insurance company. As gammaCore was not on any formulary that meant it was not covered by any insurer. CW2 also did not believe the Company had any insurance agreements by the time CW2 left the Company in June 2019.

71. CW3 was employed with electroCore from April 2015 to January 2019 as VP of Payor and Provider Strategies, working remotely but spending some time at the Company's headquarters in Basking Ridge, New Jersey. CW3's primary responsibility was to get managed care coverage for gammaCore. In July 2016, CW3 began reporting to non-party Dan Duhart ("Duhart"), Global VP of Sales and Marketing, who reported to directly to defendant Amato. CW3 explained that neither Duhart nor Amato were "experts in managed care" and that Duhart's "experience in pharma is really from the sales side, which is totally different than payor strategy and market access. It's a completely different world."

72. CW3 provided Amato and Duhart with regular updates on efforts to bring on commercial payors through telephone calls and occasionally in-person discussions at the Company's headquarters. CW3 stated that electroCore became intensely focused on trying to

secure contracts as the Company went public in June 2018. “It’s a prolonged process, which I’m not certain that everyone understood at the time. I don’t believe they wanted to understand it. They were determined that they were going public and once they did go public, they expected things to fall into place that weren’t aligned to be in place at the time.”

73. CW3 also explained that while electroCore wanted to secure reimbursement for gammaCore as a pharmacy benefit as opposed to a medical benefit, the way many payors were licensed they were required to cover Durable Medical Equipment (such as gammaCore) as a medical benefit. CW3 stated that in discussions with commercial payors, the main concern was that electroCore’s ACT 1 and ACT 2 trials for gammaCore did not meet the primary endpoint for patients with eCH. “They all mentioned the studies that were done, what was wrong with the studies. None of the studies had hit their primary endpoints.”

74. CW3 went on to explain that to demonstrate a statistically significant benefit for treating patients with eCH, electroCore had to remove chronic patients, adding that the FDA had initially instructed the Company not to combine chronic and episodic patients in the same trials, but the Company initially did so anyway. In addition, CW3 said the commercial payors had concerns over the small size of the studies and the small population of potential patients who would need gammaCore. “The payors said, ‘We don’t really need this.’”

75. CW3 also stated that electroCore’s assertion in the Registration Statement that it had agreements in place with commercial payors that would provide reimbursement for 17 million patients was incorrect and based on “some confusion about an agreement they thought they had with CVS.” According to CW3, the Company thought gammaCore would be included in CVS’s template formulary giving electroCore access to millions of patients, but later “got additional clarification that they weren’t on [CVS’s] template formulary” and “at best” would have access to

a “few million lives.” “I believe [electroCore] was probably reticent after they made public statements, they were reticent to retract it. I think they probably should have. I don’t think they were being completely accurate.”

76. CW3 added that once the CVS employee who worked with the Company on the initial agreement left CVS in early 2017, her replacement “wanted nothing to do with us.”

77. CW3 stated that the Registration Statement also failed to disclose that gammaCore was not eligible for a Healthcare Common Procedure Coding System (“HCPCS”) code and that it may not be eligible for an E-Code for Durable Medical Equipment, both of which would make it more difficult to reach agreements with commercial payors. CW3 went on to explain that “[t]he problem [was] that codes are only issued once a year. So you have to have your request for a code submitted before January 2020 to get a code effective [for] 2021. It takes a year for a code to be issued.” gammaCore failed to meet the requirements for an E-Code and did not receive the E-Code classification because of the durability of the device. The first device was disposable and gammaCore Sapphire depends on a disposable RFID card and therefore is not eligible for E-Code classification.

78. CW3 explained that to obviate the cumbersome coding process, electroCore wanted to secure reimbursement as a pharmacy benefit, but given that gammaCore is not a drug, it did not receive a National Drug Code (“NDC”) from the FDA and instead had to file to receive a unique identifier from the National Council for Prescription Drug Programs. CW3 stated that the issue with this was that First Databank, Inc. (“First Databank”), the largest database used by commercial payors, does not list non-drug NDCs along with its drug codes and instead has a unique database for devices that must be purchased separately. “So, you would have a payor who said, ‘We’d like to cover [gammaCore], but we can’t find it in the database.’”

79. CW3 stated that a draft of the Registration Statement had included information about the fact that gammaCore was not eligible for the HCPCS code and that it may not be eligible for the E-Code for Durable Medical Equipment, but the information about code eligibility was later removed. CW3 pointed out concerns with the removal to Duhart and believes Amato was informed as well. CW3 also brought the issue up at a dinner with Amato and Duhart in October 2018.

80. CW3 added, “I think that they didn’t provide investors with all the information they had and knew and had available to them when they filled out the S-1 document.” “My belief was that in the S-1 document, electroCore should have stated that they were aware that gammaCore may not fit the definition of Durable Medical Equipment, which would mean it may not be eligible for a unique E-Code under the HCPC system. And that, in my estimation, I thought that was extremely important to people who were going to invest in the company, and it was just ignored, completely ignored.”

81. CW4, a Strategic Business Consultant with electroCore from January 2015 to September 2018 who helped manage the data from the RFID cards used with the device, confirmed CW3’s concerns about the Registration Statement. “They went public before they had any payors on board. I don’t think anyone was going to pay \$500 [to use gammaCore].”

82. CW3 also expounded on the Company’s voucher program, stating that electroCore knew it needed to demonstrate demand for gammaCore and initially gave patients a one- or two-month free trial of the device by having doctors submit prescriptions, which created a record of the request that the Company could show to potential payors. gammaCore was sent to the dispensing pharmacy which would then bill the payor and ship the device to the patient and if the prescription request was denied, electroCore would pay the pharmacy for the device. “What we

wanted to do was for the doctor to submit the prescription so there would be a record of a request for a patient to [use gammaCore]. And in that way, we would demonstrate [to payors] that we were creating demand.”

83. CW3 explained that the process changed in March or April of 2018 when Duhart initiated the voucher program wherein patients received the device free of charge for one to two months, bypassing commercial payors entirely. “The doctor wrote the prescription, the prescription went into our people who were doing distribution at Asembia, and they would ship the device. But the payor never saw that because you were giving them a free device.” CW3 continued, “When we changed to the voucher program, all that happened was a dispensing pharmacy sent a device to a patient, but the insurance company was never billed. So now you haven’t created any demand.” CW3 added, “[electroCore] gave away a hell of a lot of gammaCore but you didn’t end up with any payors covering it.”

84. CW3 also commented on the price of gammaCore, calling the process used to determine pricing “backward” and explaining that it was initially priced at \$299 then maybe \$399, and then when Duhart was hired, raised to \$575. “With no market input, no focus groups, no payor strategy groups, none of that. It was really done backward. ‘How much money will we need in order to have a successful IPO?’ They worked the pricing of it backward.” CW3 added that since the patient pays for the device even if they do not have headaches, “[i]t was more like a subscription than a prescription.”

85. And, according to CW3, when Duhart asked Amato in early 2019 for more sales representatives to commercialize gammaCore, Amato told him, “We don’t have any business. We’re not generating revenue with the reps we have. We need to cut back.”

86. CW5, VP of Clinical Operations based out of the Company's headquarters from December 2018 to August 2019, stated that in May 2019, electroCore laid off almost half of its workforce, forcing the Company to stop work on some clinical trials. CW5 stated that the Company blamed the workforce reduction on the lack of funding due to the slow "uptake" of gammaCore by insurance companies. "They hadn't received approvals for their device. They kept blaming it on the uptake with the insurance companies and not getting coverage for the device as quickly as expected."

87. CW5 recalled discussions regarding the Company's efforts to reach agreements with insurance companies during senior manager meetings that took place twice a month and explained that insurance companies only provide limited time periods during each year when companies like electroCore could reach agreements with them. CW5 stated that if the window of opportunity was missed, a company would have to wait until the following year's negotiation window, "[i]t's not like with an oncology drug where you get the attention of the insurance companies right away."

88. When asked why the Company struggled with insurance companies, CW5 stated that electroCore was still trying to figure out the best patient profile that would benefit from using gammaCore. CW5 went on to explain that some data suggested that patients with migraine with accompanying sensory disturbances ("aura" headaches) would benefit more but that was a small subset of the migraine population and it was a challenge to find additional subsets of patients who would benefit from gammaCore.

89. CW6 echoed the sentiments of the other confidential witnesses. CW6 worked as a Senior Territory Business Manager for electroCore from May 2018 to April 2019, meeting with doctors in the field in hopes of getting them to prescribe gammaCore. CW6 reported to the

Regional Business Director who in turn reported to Duhart and defendant Amato. CW6 stated that the problem was that no agreements had been reached with insurers and the device was not listed on any formularies, “[t]hat was probably the demise.” About 80% of the doctors CW6 met with wanted to prescribe gammaCore, but would not write a prescription for it unless it was covered by insurance. Some doctors would take the extra steps of submitting letters on behalf of their patients and insurers would cover the cost of gammaCore about 10% of the time in those cases.

90. CW6 also recalled that Duhart led quarterly national sales conference calls during which he would provide updates on the Company’s efforts to reach agreements with insurance companies. While CW6 recalls Duhart stating that an agreement with CVS was close, it was never finalized during CW6’s tenure. “It was the same message every time we would be on national conference calls. ‘We’re still trying. We’re real close.’ That was pretty much it.”

91. CW6 also commented that CW6 and other sales representatives repeatedly told Duhart and other management that, “We have doctors that do want to prescribe [gammaCore], but their patients can’t afford \$500 a month. That was a broken record.” In summation, CW6 stated, “It doesn’t take a rocket scientist to figure out that you can’t keep giving away products and not getting coverage for it. We all knew that if we didn’t get coverage, if there’s no coverage, the company’s not going to be able to sustain.”

The Company’s Additional Use Clearance
and Trials were not Progressing as Stated by the Company

92. CW7, the Director of Clinical Affairs from April 2018 to February 2019, who worked out of the Company’s headquarters and reported to Senior Vice President of Neurology Eric Liebler (“Liebler”) who in turn reported to defendant Amato, was in charge of clinical studies, providing oversight to ensure electroCore complied with regulations and Company procedures. CW7 worked on several clinical trials, including the PREMIUM II trial, which was intended to

expand the use of gammaCore to the prevention of migraine and not just treatment. According to CW7, as of February 2019, electroCore did not have sufficient data to show that gammaCore was effective in preventing migraine, despite being discussed extensively in the 2018 Form 10-K, and touted as an upcoming mechanism to increase sales as the goal of the trial was to support use of gammaCore for migraine prevention in adults.

93. CW7 had frequent in-person conversations with Liebler regarding the trial and met once a week in the conference room to discuss trial updates as well. During the weekly meetings, one of them would type minutes which were then stored on the internal Company database in a Google document. CW7 stated that Liebler would also present updates on the trial to electroCore's senior management and Board members during weekly meetings that were attended by defendants Amato, Vraniak, and J. Errico, among others.

94. CW5 also voiced concerns over the PREMIUM II trial, specifically with the statistician electroCore had hired to advise the Company on the trial. electroCore hired a colleague of Liebler's instead of using a statistician through the clinical research organization helping run the trial and CW5 got the feeling that the statistician hired was acting to please Liebler which may have impacted the quality of the trial in terms of the data that was recorded. CW5, along with two other members of the Clinical Operations team, had a "lengthy discussion" about the concerns with Tony Fiorino ("Fiorino") in March 2019 when he was hired as the Chief Medical Officer ("CMO"), but no changes had been made by August 2019 when CW5 left the Company.

95. CW5 also commented on the FDA process, stating that it was "odd" that Liebler was the primary FDA contact when most companies CW5 previously had worked for had a Regulatory Affairs employee versus someone from Clinical. Based on CW5's conversations with

Liebler, the FDA had raised concerns about the robustness of electroCore's data to support the use of gammaCore for migraine prevention.

96. CW3 also commented on electroCore's label expansion, stating that as of January 2019, the Company did not have sufficient data to demonstrate the effectiveness of gammaCore for migraine prevention as the PREMIUM II trial was still ongoing.

Competition

97. Although electroCore claimed many competitive advantages, as stated above in ¶¶ 56-62, not only were similar devices being introduced to the market at the same time, but a new insurance-covered drug specifically used for migraine prevention was as well. In fact, CW1 stated that doctors told CW1 that gammaCore sounded like something they were already prescribing and gave the example of Cefaly. According to CW1, based on publicized results, gammaCore "seemed comparable [in effectiveness] to other devices" including Cefaly.

VI. VIOLATIONS OF SECTIONS 11 AND 15 OF THE SECURITIES ACT

98. For all claims stated within this Section VI., Lead Plaintiff expressly disclaims any allegations that could be construed as alleging fraud or intentional or reckless misconduct.

99. The Securities Act claims are brought against the following defendants: electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, the CV Defendants, and the Underwriter Defendants, *i.e.*, the Securities Act Defendants.

100. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis each participated in the preparation of and signed (or authorized the signing of) the Registration Statement and/or an amendment thereto, and the issuance thereof.

101. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are strictly liable for the materially untrue and misleading

statements incorporated into the Registration Statement. By virtue of their positions with the Company, they possessed the power and authority to control the contents of electroCore's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and market investors.

102. In the run-up to the IPO, the Underwriter Defendants: (i) assisted in the preparation and presentation of any "road show" materials designed to induce investment in the Company; (ii) conducted due diligence on the Company, including, *inter alia*, access to confidential corporate information concerning electroCore's business operations unknown to the investing public; and (iii) consulted with Company management regarding the content of the Registration Statement.

103. Pursuant to the Securities Act, the Underwriter Defendants are liable for the materially untrue and misleading statements in the Registration Statement. The Underwriter Defendants assisted electroCore and certain Individual Defendants in planning the IPO and were required to conduct an adequate and reasonable investigation into the business and operations of electroCore to participate in the IPO — a process known as a "due diligence" investigation. During the course of their due diligence investigation, the Underwriter Defendants had continual access to confidential corporate information concerning electroCore's operations and financial prospects.

104. In addition to availing themselves of virtually unlimited access to internal corporate documents, agents of the Underwriter Defendants met with electroCore's lawyers, management, and top executives and made joint decisions regarding: (i) the terms of the IPO, including the price at which electroCore shares would be sold to the public; (ii) the strategy to best accomplish the IPO; (iii) the information to be included in the Registration Statement and other offering materials; and (iv) what responses would be made to the SEC in connection with its review of the Registration Statement.

A. electroCore’s Initial Public Offering

105. electroCore filed its initial confidential draft registration statement on Form DRS with the SEC on February 13, 2018. Amended Forms DRS were then filed on April 2, 2018 and May 11, 2018, with the first registration statement on Form S-1 filed with the SEC on May 21, 2018. electroCore filed amendments to the Form S-1 on June 5, 2018, June 11, 2018, and June 15, 2018. The Registration Statement was declared effective by the SEC on June 21, 2018.

106. On June 25, 2018, electroCore filed with the SEC a prospectus pursuant to Rule 424(b)(4) (the “Prospectus”), commencing its IPO of 5.2 million shares of common stock at a price of \$15.00 per share. The Registration Statement stated that the intended use of the IPO proceeds was to be as follows: (i) \$35 million to fund commercialization of products; (ii) \$10 million to fund expansion of its clinical programs; (iii) \$3 million to fund the build out of a specialty distribution channel for the launch of gammaCore Sapphire in the third quarter of 2018; and (iv) the remaining balance for working capital and other corporate purposes.

107. On June 28, 2018, electroCore announced that the Underwriter Defendants had chosen to exercise their option to sell an additional 780,000 shares. In total, electroCore issued and sold 5,980,000 shares of common stock, reaping net proceeds of approximately \$77.7 million.

**B. Defendants Used Material Misstatements and Omissions
in the Registration Statement to Sell electroCore to the Investing Public**

108. electroCore’s Registration Statement garnered the Company net proceeds of over \$77.7 million and permitted the Company to continue to operate. Unbeknownst to Lead Plaintiff and the Class, the Registration Statement was negligently prepared, containing numerous material false and misleading statements and omitting material facts.

109. The Registration Statement touted the Company’s competitive advantages of its “novel and propriety self-administered bioelectronic therapy” and its business strategies that would

permit electroCore not only to increase sales of gammaCore for its current FDA approved uses through increasing insurance coverage, among other things, but also to obtain additional approved uses.

110. According to the Registration Statement, electroCore and the “novel” gammaCore product had certain “competitive strengths” as follows:

- ***Our non-invasive therapy unlocks the long-held potential of VNS.*** VNS therapy can, for the first time, be delivered comfortably through the skin using gammaCore. This eliminates the need for costly, invasive surgery that has been reserved for the most refractory patients, requiring the implantation of a permanent medical device.
- ***Commercializing our therapy through traditional pharmaceutical channels.*** Our non-invasive delivery modality permits medical professionals to prescribe VNS through the same channel they would any other specialty medication. Refills delivered on a monthly basis enable us to seek widespread commercial payor coverage and reimbursement under a traditional pharmaceutical model. We have agreements in place with commercial payors that we believe, based on our estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives with such number expected to increase to as many as 45 million lives under these agreements over the next several calendar quarters.
- ***Highly scalable and low investment manufacturing with digital refills.*** Our low manufacturing and assembly costs allow us to scale to meet demand with minimal additional investment. Refills through RFID or Bluetooth may offer attractive gross margins.
- ***Potential for rapid label expansion in headache and regulatory approval in additional indications.*** In April 2017, the FDA cleared gammaCore for commercial sale in the United States and established a new therapeutic category: external vagal nerve stimulator for the treatment of headache. Through an expedited pathway, gammaCore received clearance for the acute treatment of pain associated with migraine in January 2018. We believe a similar regulatory pathway may be available to us for additional indications in rheumatology.

* * *

- ***Highly experienced management team.*** Our management team includes executives with significant experience in the pharmaceutical and medical device industries, including positions at Pfizer Inc., Merck & Co., Novartis

International AG, Stryker Corporation and Zimmer Biomet. Members of our team have been involved in the launch and marketing of products including Motrin, Celebrex, and the migraine drugs Axert and Maxalt. Our team's pharmaceutical experience in clinical development, sales, marketing and reimbursement, and its medical device experience in research, development and regulatory affairs, allow us to pursue our strategy and growth plans.

111. The Registration Statement also noted:

Important advantages of gammaCore over other acute treatments for migraine and episodic cluster headache include its ease of use and suitability to be applied for as many attacks as a patient experiences per day, without the frequency-of-use restrictions and contraindications associated with other treatments.

112. The Registration Statement included material information on the markets the Company was focusing on, stating, *inter alia*, that the addressable market in 2018 for the treatment of migraines and cluster headaches was approximately \$3.8 billion and \$400 million, respectively, and that:

Migraine is a debilitating primary headache condition characterized by severe throbbing pain or a pulsing sensation, usually on one side of the head. Migraine affects approximately 12% of the adult population globally and disproportionately impacts women of childbearing years. In the United States, there are approximately 36 million migraine sufferers. Medications used to treat migraine include triptans, ergotamines, and antiepileptic medications. Despite the fact that neurologists recognize the limited efficacy of, and the potential for abuse associated with, opioids, this class of medication continues to be prescribed for migraine at high rates, particularly in emergency departments. According to the U.S. Pharmacist, a leading pharmacy publication, upwards of 60% of the migraine patient population is dissatisfied with, or has contraindications to, the current standard of care migraine treatments. We estimate the addressable market for the acute treatment of migraine in the United States in 2018 will be approximately \$3.8 billion. Five million migraine sufferers are treated annually by approximately 1,100 U.S. headache specialists, primarily neurologists.

113. In addition to full explanations of the marketability of gammaCore for applications other than acute treatment of CH and migraines, the Securities Act Defendants included the following chart in the Registration Statement, highlighting the Company's numerous market applications:

Table 1: Our Headache Pipeline

Indication	Preclinical / Pilot Trials	Pivotal Trials	FDA Clearance	Commercial Launch ¹	Key Milestones
Acute Treatment of Episodic Cluster Headache					<ul style="list-style-type: none"> • FDA clearance April '17 • Commercial registry initiated 3Q '17 • Full commercial launch expected 3Q '18
Acute Treatment of Migraine					<ul style="list-style-type: none"> • FDA label expansion January '18 • Full commercial launch expected 3Q '18
Migraine Prevention					<ul style="list-style-type: none"> • Final PREMIUM trial data publication expected 2H '18 • 2nd pivotal trial initiation expected 2H '18
Migraine in Adolescents					<ul style="list-style-type: none"> • Pivotal trial initiation expected 2H '18
Post-Traumatic Headache					<ul style="list-style-type: none"> • Initial preclinical studies in progress • Pilot trial initiation expected 2H '18

114. Under a section titled “Our Strategy,” the Registration Statement touted electroCore’s “key elements” in becoming a market leader, including how certain strategies were *already in place*,¹ including “agreements with commercial payors” providing for reimbursement for 17 million patients:

Our goal is to be a leader in bioelectronic medicine by using our proprietary non-invasive VNS platform therapy to deliver better patient outcomes. The key elements of our strategy include:

- ***Drive acceptance of our gammaCore products as a leading headache therapy, introducing it in cluster headache and expanding into migraine.*** We plan to establish gammaCore as the first-line treatment for episodic cluster headache patients, who have few alternative treatment options available to them. We will then leverage this position to expand into the broader headache market for migraine in the third quarter of 2018.
- ***Drive reimbursement of our therapy.*** We are actively engaging with over 50 national and regional commercial insurance payors in the United States with the goal of securing reimbursement coverage as a pharmacy benefit. We have agreements with commercial payors in place that we believe, based on our estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives, with such number expected to increase to as many as 45 million lives under these agreements over the next several calendar quarters.

¹ Unless otherwise noted, all emphasis is added.

- ***Build a leading commercial presence.*** We are establishing a robust commercial capacity, including a specialty distribution channel with a concierge service to quickly onboard patients and manage payor interactions, and a direct sales force to target high prescribing neurology specialists and headache centers.

115. Similarly, under a section titled “Commercialization,” the Registration Statement explained the Company’s “commercial strategy” which included ***current*** “agreements with commercial payors” and ***current*** access to “17 million commercial lives” with additional access to “45 million lives” expected “over the next several calendar quarters:”

We believe the significant unmet need and highly-targeted market of episodic cluster headache represents an ideal entry point for our therapy into the headache market, providing an opportunity to gain relevance with treating clinicians in order to support an expansion into migraine. Our commercial strategy will initially focus on the following priorities:

- ***Drive advocacy of gammaCore as a leading headache therapy.*** Our strategy is to establish gammaCore as a preferred treatment option, initially in episodic cluster headache and expanding into migraine. We are developing advocacy for gammaCore among key opinion leaders through our clinical program and initial product registry. We currently have in excess of 300 clinicians trained on gammaCore use and over 600 unique prescribers. Of these, 50 are key opinion leaders who will lead a series of programs to educate their colleagues on our clinical data and our specialty pharmacy distributor and its national network of specialty pharmacies.
- ***Drive reimbursement of our therapy.*** Through our product registry and initial commercialization efforts we are generating prescriptions and patient claims to prompt commercial payors to initiate reimbursement policies for gammaCore. We have engaged over 50 national and regional commercial insurance payors in the United States with the goal of obtaining reimbursement coverage as a pharmacy benefit. gammaCore is currently the subject of agreements with commercial payors that we believe, based on our estimates, will provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives, with such number expected to increase to as many as 45 million lives under those agreements over the next several calendar quarters. In addition, our access negotiations have entered the active clinical review stage with more than a dozen additional insurance plans covering approximately 120 million additional commercial lives.
- ***Build a leading commercial presence.*** We have partnered with an established specialty pharmacy distributor to provide physician and patient

support to quickly onboard patients and manage payor interactions. This support includes adjudication of all gammaCore prescriptions, payor claims for reimbursement, and patient support and training. Our sales force targets high-prescribing U.S. neurology practices and headache centers. We currently have a sales force of 18, with three medical science liaisons. We plan to hire an additional 14 territory business managers, who will ultimately cover 6,400 high-prescribers of headache medications.

116. In addition, the Registration Statement explained:

Following our initial FDA clearance, our commercial strategy has been to establish gammaCore as a first-line treatment option for episodic cluster headache patients, who have few alternative treatment options available to them. *This strategy is supported by a product registry initiated in July 2017 to build advocacy among key opinion leaders in 55 leading headache centers in the United States, and to generate patient demand in the form of prescriptions submitted to payors. We intend to leverage this advocacy as we expand into the broader headache market for both migraine and cluster headache in the third quarter of 2018.*

* * *

As part of our broad payor engagement strategy we are seeking to secure pharmacy benefit reimbursement for our therapy by working with both commercial payors and pharmacy benefit managers, also known as PBMs. PBMs are third party groups who manage the pharmacy benefits offered by the commercial payors. In the U.S. market, there are three major large PBMs. We have entered into an agreement with one of these major PBMs, which manages approximately 60 million U.S. lives. Pursuant to this agreement, gammaCore will be covered, depending on the commercial payor that the PBM serves, and the specific plan, for commercially covered U.S. patients, as either a preferred brand or non-preferred brand. As a preferred brand, or Tier 2 product, the coverage would require a monthly copayment paid by the patient of approximately \$30. As a non-preferred brand, considered a Tier 3 product, the monthly copayment would likely be between \$60 and \$75. Under this agreement, we anticipate, based on our estimates, that approximately 15 million U.S. commercial lives will shortly have access to our therapy as either a Tier 2 or Tier 3 product, and we anticipate this number will grow to at least 45 million lives under this agreement over the coming quarters as we, together with this PBM, engage with additional commercial payors to position our product across the payors' plans. The strategy of engaging with payors and PBMs is continuing as we engage the other major PBMs and payors towards the goal of increasing patient access to our therapy.

117. The Company's increasing expenses were attributed to the purported "commercialization" efforts as well:

In anticipation of clearance from the FDA and commencement of commercial sales in the United States, we incurred a significant increase in compensation costs as additional personnel were hired to oversee the execution of the commercial plan in the United States and Europe. Significant expenses include costs associated with marketing and advertising, salesforce, professional fees for legal services, including legal services associated with our efforts to obtain and maintain broad protection for the intellectual property related to our products, rent, compliance, payor reimbursement development, accounting services, and consulting fees.

* * *

Research and development expenses increased \$0.6 million to \$2.3 million for three months ended March 31, 2018, from \$1.7 million for the three months ended March 31, 2017. This increase was primarily the result of an increase in headcount and increased compensation expenses related to personnel of \$563.0 thousand, an increase in research studies of \$200.0 thousand, which was offset by a decrease in other related expenses. We plan to increase our research and development expenses in 2018 to support product development, product enhancements and future clinical studies, to further develop and update our existing technologies and to expand our gammaCore therapy for the treatment of other indications, including additional headache conditions and rheumatology.

118. Regarding current gammaCore sales, the Registration Statement stated, in relevant part:

In February 2018 we began a formal physician training program highlighting the clinical evidence and benefits of gammaCore for the acute treatment of pain associated with migraine and episodic cluster headache. Concurrently, to incentivize these physicians to issue prescriptions and increase market penetration, we began a voucher program providing new patients with a one-time 31-day therapy at no charge to the patient. While the voucher program has increased demand, the transaction price for each unit sold through the voucher program is reduced by the amount of the one-time free 31-day therapy which offsets the effects of the increased demand for gammaCore. Our revenue reflects only gammaCore units sold either for new patients, or existing patients refills, that are not related to our voucher program.

119. And, relatedly, while disclosing declining sales revenues in the first quarter of 2018, the Company attributed the trend to the voucher program rather than to competition and also claimed that the voucher program would be temporary:

Net sales decreased \$35.7 thousand to \$81.2 thousand for three months ended March 31, 2018, from \$116.9 thousand for the three months ended March 31, 2017. The decrease is primarily due to a reduction in the transaction price related to the

cost of voucher program and the co-payment assistance program. Net sales are not recognized for gammaCore units redeemed, or estimated to be redeemed under the Company's voucher program.

120. The Registration Statement, including the statements in ¶¶ 109-19 above, was materially false and/or misleading and omitted to disclose material information necessary to make its statements not misleading. Specifically, the Registration Statement was materially misleading due to the following:

- (i) gammaCore did not enjoy any competitive advantages over other treatments for eCH and migraines. At the same time gammaCore was entering the market, several other similar medical devices also had entered or were entering the market, with several already approved for *both* acute and preventative treatment and “comparable [in effectiveness].” In addition, a new category of drugs had already, or were just about to, receive FDA approval at the time of electroCore’s IPO. These CGRP drugs, including Aimovig, which was specifically designed for migraine prevention, the larger market electroCore planned to pursue, was not only regarded as more effective than gammaCore, but was covered by insurance, a key prohibitive issue physicians had with gammaCore. Although facing these competitors, the Registration Statement contained paltry mention of such competition and nowhere discussed the competitive advantages certain of those drugs had over gammaCore in being covered by insurers and the increasing pricing pressure the introduction of these products was causing the Company.
- (ii) Relatedly, the Registration Statement failed to disclose that gammaCore was most often regarded as a supplemental treatment instead of a primary treatment for migraines. Cantor Fitzgerald pointed this out in several reports, stating in its initiating report that the “Company [is] planning to target [gammaCore] as a

adjunctive treatment early on (for combinations with CGRPs, botox, and other current treatments) . . .” and in an October 22, 2018 report stated “[w]e see the biggest potential in adjunctive therapy alongside current and emerging treatments including CGRP mAbs.” Defendant Amato was even forced to admit after the IPO that CVS would only cover gammaCore if a “patient has failed at least three other prescribed medications.” Thus, gammaCore was not a primary treatment as the Securities Act Defendants portrayed it to be in the Registration Statement.

- (iii) The Registration Statement failed to disclose and/or misrepresented numerous key aspects of the Company’s purported “business strategy” and “commercialization” of gammaCore.
 - (a) *First*, the Registration Statement misrepresented the Company’s relationships with insurance companies and commercial payors, claiming, *inter alia*, to have “agreements” in place and access to reimbursement for 17 million of patients. In reality, electroCore’s agreements were limited, with, for example, CVS not including gammaCore on CVS’s template formulary and requiring patients to have tried and had no success with three other treatments before gammaCore.
 - (b) *Second*, electroCore was having a multitude of other issues in obtaining insurance coverage, but failed to disclose any of the issues in the Registration Statement. For example, as explained in ¶¶ 77-78, there were issues with eligibility for certain diagnostic codes which made it more difficult to reach agreements with commercial

payors. In fact, defendant Amato later admitted that a standard that “universalizes our codes for inclusion in all pharmacopoeia” was not developed ***until 2019*** and that First Databank, the largest database used by commercial payors, did not agree to “build[] a third database which [would] include all the codes for [gammaCore]” until 2019 and that it would not even be available until 2020.

- (c) *Third*, as a result of the above issues, and the Company’s attempts to promote gammaCore as both a durable medical device and a pharmacy benefit, physicians were reticent to prescribe gammaCore because reimbursement was hard to obtain and took additional steps that only about 10% of doctors were willing to undertake. The increased burdens on physicians also increased expenses for electroCore as the Company’s personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage.
- (d) *Fourth*, the Registration Statement failed to disclose that electroCore was dependent on its voucher program to grow sales, and that not only was the voucher program failing to increase revenues and was actually increasing losses, it was also substantially impeding the Company’s progress with payors. Specifically, the voucher program bypassed the insurance companies so potential payors never saw the demonstrated demand for gammaCore, making it less likely for them to agree to coverage.

- (iv) The Registration Statement also failed to disclose that all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable.
- (v) The Registration Statement also failed to disclose that electroCore's CEO and CFO, as well as other senior management, were poised to leave the Company soon after the IPO.
- (vi) As a result of the foregoing, the Securities Act Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

121. The Registration Statement was also materially untrue and misleading because it failed to meet the requirements of Item 303 of Regulation S-K. 17 C.F.R. § 229.303(a)(3)(ii). Item 303 requires issuers to disclose events or uncertainties, including any known trends, that have had or are reasonably likely to cause the registrant's financial information not to be indicative of future operating results. The Securities Act Defendants failed to sufficiently disclose events or uncertainties, including any known trends, as described in ¶ 120 above.

122. Additionally, Item 105 of SEC Regulation S-K, 17 C.F.R. § 229.105, required, in the "Risk Factors" section of the Registration Statement, a discussion of the most significant factors that make the Offering risky or speculative and that each risk factor adequately describe the risk. The Securities Act Defendants failed to adequately describe the risks as described in ¶ 120 above.

C. Events and Disclosures Following the Offering

123. On March 8, 2019, electroCore issued a press release, titled "electroCore Appoints Multiple Industry Veterans to Key Management Positions," announcing that defendant Vraniak was resigning "to pursue other professional opportunities," appointing defendant Posner as the

replacement CFO, and announcing that the Company's CMO, Staats, would transition to Senior Executive Advisor of Medical and Government Affairs with Fiorino replacing him as CMO.

124. As more fully described in Section VII.B. below, beginning with electroCore's first quarter 2019 earnings release on May 14, 2019, electroCore's true position was revealed to investors. Indeed, less than one year after its IPO and purported "competitive advantages" and agreements with payors, the Company announced a comprehensive redeployment and cost reduction plan. And, on June 10, 2019, the Company announced that defendant Amato would be "stepping down" as CEO, although remaining with electroCore "for a transition period."

125. On July 15, 2019, the Company announced the filing of a Form S-3 with the SEC for the issuance of up to \$50 million worth of the Company's common stock, senior or subordinated debt securities, preferred stock and/or warrants.

126. By the commencement of this action, electroCore stock was trading as low as \$1.25 per share, a nearly 92% decline from the \$15.00 per share IPO price.

D. Causes of Action Under Sections 11, 12(a)(2) and 15 of the Securities Act

COUNT I

**For Violations of Section 11 of the Securities Act
(Against electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the Underwriter Defendants)**

127. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein. This Count is predicated upon electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the Underwriter Defendants' strict liability for making false and materially misleading statements and omissions in the Registration Statement.

128. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff

does not allege for this Count that the Securities Act Defendants named herein had scienter or fraudulent intent, which are not elements of this claim.

129. This Count is brought pursuant to Section 11 of the Securities Act on behalf of all persons who purchased electroCore common stock pursuant to and/or traceable to the Company's IPO, in which shares registered under the Registration Statement were sold.

130. As alleged, the Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary in order to make the statements not misleading, and omitted to state material facts required to be stated therein.

131. As issuer of the shares, electroCore is strictly liable to Lead Plaintiff and the Class for the misstatements and omissions in the Registration Statement.

132. Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are strictly liable for the contents of the Registration Statement based upon their status as officers and/or directors of the Company and/or because they signed or authorized the signing of the Registration Statement on their behalf pursuant to Section 11(a)(1)-(3) of the Securities Act. Each of these defendants was responsible for the contents and dissemination of the Registration Statement, which were inaccurate and misleading, contained untrue statements of material facts, and omitted facts necessary to make the statements made therein not misleading, and omitted to state material facts required to be stated therein. Each of these defendants had a duty to make a reasonable and diligent investigation of the truthfulness and accuracy of the statements contained in the Registration Statement and ensure that they were true and accurate and not misleading. In the exercise of reasonable care, these defendants should have known of the material misstatements and omissions contained in the Registration Statement.

Accordingly, each of these defendants is liable to Lead Plaintiff and the other members of the Class.

133. The Underwriter Defendants are strictly liable for the contents of the Registration Statement as named underwriters pursuant to Section 11(a)(5) of the Securities Act.

134. None of the Securities Act Defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement and identified at ¶¶ 109-19 were true and without omissions of any material facts and were not misleading.

135. By reason of the conduct alleged herein, each the Securities Act Defendants named in this Count violated, and/or controlled a person who violated, Section 11 of the Securities Act.

136. Lead Plaintiff and other members of the Class acquired electroCore common stock pursuant and/or traceable to the Registration Statement for the IPO.

137. Lead Plaintiff and the Class have sustained damages. The value of electroCore's common stock has declined substantially below the Offering price and below the price Lead Plaintiff and the other members of the Class paid for their electroCore common stock subsequent to and due to the Securities Act Defendants' violations of law.

138. At the time of their purchases of electroCore common stock, Lead Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts. Less than one year has elapsed from the time that Lead Plaintiff discovered or reasonably could have discovered the facts upon which this Complaint is based to the time of the filing of the initial complaint in this action. Less than three years has elapsed between the time that the securities upon which this Count is brought were offered to the public and the time Lead Plaintiff filed this Complaint.

139. By virtue of the foregoing, Lead Plaintiff and the other members of the Class are entitled to damages under Section 11 as measured by the provision of Section 11(e), from the Securities Act Defendants and each of them, jointly and severally.

COUNT II
For Violations of Section 12(a)(2) of the Securities Act
(Against electroCore and the Underwriter Defendants)

140. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein.

141. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff does not allege for this Count that electroCore or the Underwriter Defendants had scienter or fraudulent intent, which are not elements of this claim.

142. This Count is brought pursuant to Section 12(a)(2) of the Securities Act on behalf of all persons who purchased electroCore common stock pursuant to and/or traceable to the Company's IPO against electroCore and each of the Underwriter Defendants.

143. The Prospectus contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted material facts required to be stated therein. The actions of solicitation by the defendants named in this Count include participating in the preparation of the false and misleading Prospectus, roadshow, and marketing of electroCore's common stock to investors, such as Lead Plaintiff and the other members of the Class.

144. The defendants named in this Count owed to the purchasers of electroCore common stock, including Lead Plaintiff and other members of the Class, the duty to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission to state a material fact required to be stated in order to

make the statements contained therein not misleading. By virtue of each of these defendants' failure to exercise reasonable care, the Prospectus contained misrepresentations of material facts and omissions of material facts necessary to make statements therein not misleading.

145. Lead Plaintiff and the other Class members did not know, nor could they have known, of the untruths or omissions contained in the Prospectus.

146. The defendants named in this Count were obligated to make a reasonable and diligent investigation of the statements contained in the Prospectus to ensure that such statements were true and that there was no omission of material fact required to be stated in order to make the statements contained therein not misleading. None of the defendants named in this Count made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Prospectus were accurate and complete in all material respects. Had they done so, these defendants could have known of the material misstatements and omissions alleged herein.

147. This Count is brought within one year after discovery of the untrue statements and omissions in the Prospectus and within three years after the Company's shares were sold to the Class in connection with the Offering.

148. By reason of the conduct alleged herein, the defendants named in this Count violated Section 12(a)(2) of the Securities Act. As a direct and proximate result of such violation, Lead Plaintiff and the other members of the Class who purchased electroCore common stock pursuant and/or traceable to the Prospectus sustained substantial damages in connection with their share purchases. Accordingly, Lead Plaintiff and the other members of the Class who hold shares issued pursuant to the Prospectus have the right to rescind and recover the consideration paid for their shares with interest thereon or damages as allowed by law or in equity. Class members who have sold their electroCore shares seek damages to the extent permitted by law.

COUNT III

For Violations of Section 15 of the Securities Act

(Against Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants)

149. Lead Plaintiff repeats and realleges each of the allegations contained above as if fully set forth herein.

150. This Count does not sound in fraud. Any proceeding allegations of fraud, fraudulent conduct, or improper motive are specifically excluded from this Count. Lead Plaintiff does not allege for this Count that the defendants named herein had scienter or fraudulent intent, which are not elements of this claim.

151. This Count is brought pursuant to Section 15 of the Securities Act against defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants.

152. Each of the individual defendants named in this Count acted as a controlling person of electroCore within the meaning of Section 15 of the Securities Act by virtue of his or her position as a director and/or senior officer of electroCore. By reason of their senior management positions and/or directorships at the Company, as alleged above, these defendants, individually and acting pursuant to a common plan, had the power to influence and exercised the same to cause electroCore to engage in the conduct complained of herein. Further, the defendants' positions made them privy to and provided them with actual knowledge of the material facts concealed from Lead Plaintiff and the Class. By reason of such conduct, the defendants named in this Count are liable pursuant to Section 15 of the Securities Act.

153. Each of the individual defendants named in this Count was a culpable participant in the violations of Section 11 of the Securities Act alleged in Count I above, based on their having

signed the IPO Registration Statement and having otherwise participated in the process which allowed the IPO to be successfully completed.

154. The CV Defendants each had the ability to influence the polices and management of the Company at all relevant times by means of their control over the Company through the entities' managing members, defendants J. Errico and T. Errico. The CV Defendants also had a financial interest in taking the Company public and were critical to effectuating the Offering.

155. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement and identified at ¶¶ 109-19 were true and without omissions of any material facts and were not misleading.

156. By virtue of the conduct alleged herein, defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, and the CV Defendants are liable for the aforesaid wrongful conduct and are liable to Lead Plaintiff and the Class for damages suffered as a result of the primary Securities Act violations of electroCore.

VII. VIOLATIONS OF SECTIONS 10(b) AND 20(a) OF THE EXCHANGE ACT

157. The allegations contained in ¶¶ 158-238 below are made with respect to Lead Plaintiff's claims under Sections 10(b) and 20(a) of the Exchange Act only. Lead Plaintiff disclaims any reliance upon these allegations or incorporation of these allegations in the Securities Act claims.

158. These Exchange Act claims are brought against the following defendants: electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis, *i.e.*, the Exchange Act Defendants.

159. The Exchange Act Defendants (with the exception of Posner) are makers of the statements contained in the Registration Statement. electroCore is the issuer of the statements,

and Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis signed their names to those statements (or authorized the signing of), indicating that each was a maker thereof. The materially false and misleading statements and omissions as described in Section V. above and the reasons for those statements' falsity and materiality are expressly incorporated and re-alleged as if fully set forth herein.

A. Additional Materially False and Misleading Misrepresentations and Omissions Actionable Under the Exchange Act

160. On August 13, 2018, electroCore issued a press release titled “electroCore, Inc. Announces Second Quarter Financial Results,” (the “August 2018 Press Release”) stating in relevant part:

Second Quarter 2018 and Recent Highlights

- Second quarter net sales was \$393,000, an increase of \$217,000 over second quarter of 2017
- Completed initial public offering of our common stock, receiving net proceeds of approximately \$77.7 million after deducting underwriting discounts, commissions and offering costs

* * *

“I am encouraged by our second quarter financial results,” said Frank Amato, Chief Executive Officer. “I believe our successful IPO will not only enable us to expand our commercial presence, but also allows us to build upon our growing list of positive clinical studies.”

Second Quarter Financial Results

Net sales for the three months ended June 30, 2018 increased \$217,000 from the second quarter of 2017. The growth in sales was due to an increase in the company’s sales force and the January 29th FDA clearance for an expanded label for gammaCore as an acute treatment for pain associated with migraine in adult patients.

Gross profit for the second quarter of 2018 was \$153,000, up from \$138,000 in the same period of the prior year.

Total operating expenses for the second quarter of 2018 were \$16.4 million, an increase of \$8.8 million compared to the same period in 2017. The increase in operating expenses was driven primarily by costs related to expansion of the

company's sales and additional stock based compensation expense, due to the corporate conversion.

Operating loss in the second quarter of 2018 was \$16.2 million, as compared to an operating loss of \$7.4 million in the second quarter of 2017.

Cash, cash equivalents, and short-term investments were \$95.8 million as of June 30, 2018.

161. On August 14, 2018, electroCore filed with the SEC its quarterly report on Form 10-Q for the quarter ended June 30, 2018 ("2Q18 10-Q"), signed by defendants Amato and Vraniak, and reiterating the financial results as reported in the August 2018 Press Release. Amato and Vraniak also signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") attesting to the accuracy of the financial reporting and the disclosure of any material changes to the Company's internal control over financial reporting, and stating that the quarterly report did "not contain any untrue statement of material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading;" that "[a]ny fraud, whether or not material, that involves management or other employees who have a significant role in the [Company's] internal control over financial reporting" was disclosed and that "the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

162. The statements in ¶¶ 160-61 above were materially false and/or misleading and failed to disclose material adverse facts. Among other things, the August 2018 Press Release and 2Q18 10-Q failed to disclose to investors: (i) that gammaCore did not enjoy any advantages over other acute treatments for migraines and episodic cluster headaches; (ii) that gammaCore's voucher program was not effective in increasing adoption of gammaCore and in fact was negatively effecting reimbursement by payors, making it appear as if the device was more popular than it actually was, and increasing Company costs; and (iii) that the Company's business plan and

strategy was unsustainable because electroCore lacked sufficient revenue to be profitable. *See also ¶ 179.*

163. On November 13, 2018, the Company issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC titled, “electroCore, Inc. Announces Third Quarter Financial Results” (the “November 2018 Press Release”). The November 2018 Press Release stated, in relevant part:

Third Quarter 2018 and Recent Highlights

- Generated 4,516 gammaCore® prescriptions in the third quarter of 2018, with over 11,000 prescriptions written as of October 31, 2018
- Nearly 1,500 unique prescribing physicians through the third quarter of 2018, an increase of 48% from the second quarter
- Launched reloadable and rechargeable gammaCore Sapphire across the U.S. market
- Submitted 510(k) application to the FDA for the prevention of cluster headache
- *Commercial payer coverage for 35 million lives beginning in the first quarter of 2019*
- National Institute of Health and Care Excellence (NICE) publication advising gammaCore for the treatment of cluster headache in the U.K.

“We are pleased with our performance in the third quarter and are encouraged by the positive prescription trends we are generating while we progress forward several clinical and strategic initiatives,” said Frank Amato, Chief Executive Officer. *“With continuing discussions and negotiations for payer coverage for an additional 90 million lives, and our increasing base of prescribing physicians, we are well positioned for gammaCore to be an early option for patients suffering from migraine and episodic cluster headaches.”*

Third Quarter Financial Results

electroCore recognized \$150,972 in net sales for the three months ended September 30, 2018. *The decrease in net sales of \$132,267 versus the third quarter of 2017 contrasts with the significant increase in prescriptions during the same period as a result of a vast majority of prescriptions being dispensed under our patient voucher and copay assistance programs, as the Company continues negotiations with commercial payers for formulary coverage of gammaCore. The Company expects this trend to be temporary, as increased numbers of patients are expected to obtain commercial prescription coverage for gammaCore starting in January 2019.* The Company dispensed approximately \$1.7 million in product sales value to patients through the patient voucher program.

Gross profit for the third quarter of 2018 was \$53,905, down from \$154,921 in the same period of the prior year.

Total operating expenses for the third quarter of 2018 were \$13.6 million, an increase of \$7.5 million compared to the same period in 2017. The increase in operating expenses was driven primarily by costs related to expansion of the company's sales and marketing functions.

Operating loss in the third quarter of 2018 was \$13.2 million, as compared to an operating loss of \$12.4 million in the third quarter of 2017.

Cash, cash equivalents, and short-term investments were approximately \$80.5 million as of September 30, 2018.

164. The Company also held an earnings conference call on November 13, 2018. On the earnings call, defendant Amato discussed the Company's commercial payor agreements, stating, in relevant part:

So where are we with the commercial payers and PBMs? *Currently we have multiple reimbursement agreements in place. The first of which is the CVS Caremark agreement, which will go into effect on January 1, 2019. Under this agreement, we have been advised that approximately 30 million of the 65 million U.S. individuals managed by CVS Caremark will have access to our therapy as a Tier 3 product beginning in January of 2019.* Potential access to the remaining 35 million lives will be gained through continuing negotiations with the payers within the CVS network.

165. Defendant Vraniak discussed the financial results and voucher program, stating:

For the quarter ending September 30, 2018, we reported GAAP revenue of \$150,972, a decrease of \$132,267 from the third quarter of 2017. *This decrease is primarily due to the contra-revenue remaining as a result of our voucher program that extended into mid-July. Under this voucher program through mid-July, we would reimburse the specialty pharmacy for patient cost of gammaCore therapy at the time of dispense. This would be the basis for recognizing contra-revenue against products sold previously to our distributor.* In mid-July, we shifted to the use of a free voucher program free voucher units, thereby, eliminating the need to reimburse the pharmacy for patient cost and the need to book contra-revenue. The cost of these units dispensed under the voucher program after mid-July will then book to promotional expense. And in this way, it appears much more like a sample program.

166. On November 14, 2018, electroCore filed with the SEC its quarterly report on Form 10-Q for the quarter ended September 30, 2018 (the "3Q18 10-Q"), affirming the financial results as reported in the November 2018 Press Release. The 3Q18 10-Q was signed by defendants Amato

and Vraniak and contained their signed certifications, containing the same statements as in ¶ 161, pursuant to SOX.

167. The statements in ¶¶ 163-166 above were materially false and/or misleading and failed to disclose material adverse facts. Among other things, the November 2018 Press Release, related earnings conference call, and 3Q18 10-Q failed to disclose to investors: (i) that gammaCore did not enjoy any advantages over other acute treatments for migraines and episodic cluster headaches and in fact was most often regarded as a supplemental treatment instead of a primary treatment; (ii) that gammaCore's voucher program was not effective in increasing adoption of gammaCore and in fact was negatively effecting reimbursement by payors, making it appear as if the device was more popular than it actually was, and increasing Company costs; (iii) that the Company's agreements with payors had restrictions limiting the patient population the payors would cover; (iv) that there were numerous issues with payor formularies and diagnostic codes impeding payor reimbursement agreements; and (v) that the Company's business plan and strategy was unsustainable because electroCore lacked sufficient revenue to be profitable. *See also* ¶ 179.

168. On March 27, 2019, electroCore issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC titled "electroCore Announces Fourth Quarter and Full Year 2018 Financial Results," announcing the Company's financial results for the quarter and year ended December 31, 2018 (the "March 2019 Press Release"). The March 2019 Press Release stated in relevant part:

"During the fourth quarter, we continued to execute on our commercial growth plan, led by our ongoing progress toward increasing covered lives through productive discussions with national and regional payers," said Frank Amato, Chief Executive Officer of electroCore. *"Notably, our fourth quarter results do not reflect the addition of covered lives from CVS Caremark, Highmark and the recently announced Federal Supply Schedule contract, all of which commenced reimbursement of gammaCore® beginning in the first quarter 2019. Our leading indicators in our approved indications of migraine and cluster headache – which*

together represent a four billion dollar market opportunity – are very strong, and coupled with our R&D initiatives targeting additional indications in headache conditions and rheumatoid arthritis, we believe we have established a solid foundation from which to drive future growth. Vagus nerve stimulation represents an effective, drug-free and non-invasive alternative treatment modality that we believe has broad clinical utility across a range of underserved medical conditions, and we intend to make gammaCore® the therapy of choice for patients who stand to benefit from this innovative therapy.”

Fourth Quarter and Full Year 2018 Financial Results

For the quarter ending December 31, 2018, electroCore reported net sales of \$368 thousand, an increase of \$134 thousand from the fourth quarter of 2017 and an increase of \$217 thousand from the third quarter of 2018, reflecting increased sales of gammaCore Sapphire.

Total operating expenses for fourth quarter of 2018 were \$15.9 million, which is an increase of \$8.4 million compared to the same period in 2017 and an increase of \$2.3 million from the third quarter of 2018. The increase in operating expense was driven primarily by costs related to the expansion of the company's sales and marketing functions.

Operating loss for the fourth quarter of 2018 was \$15.7 million as compared to an operating loss of \$7.5 million in the fourth quarter of 2017 and \$13.6 million in the third quarter of 2018.

For the full year, net sales were \$993 thousand, a 22% increase as compared to \$811 thousand for the full year 2017. This increase in net sales is attributable to higher prescriptions as a result of the full commercial launch of gammaCore in the U.S.

Full year 2018 gross profit was \$414 thousand as compared to \$293 thousand for the full year 2017.

Total operating expenses were \$55.0 million for the full year 2018 as compared to \$25.9 million for the full year 2017. The increase in operating expense was driven primarily by costs related to the expansion of the company's sales and marketing functions.

Operating loss for the full year 2018 was \$54.6 million as compared to an operating loss of \$25.6 million for the full year 2017.

Cash and cash equivalents and marketable securities at December 31, 2018 totaled \$68.6 million.

169. The Company also held an earnings conference call on March 27, 2019 during which defendant Amato touted the Company's purported business strategy successes and competitive advantages, stating, in relevant part:

We've made significant progress since our initial public offering in June 2018, building a commercial infrastructure to drive awareness of gammaCore amongst payers, physicians and patients. And today, I'm pleased to say that these efforts have begun to establish a solid foundation for future growth. I'll begin with a few highlights from the fourth quarter and full year.

During the fourth quarter of 2018, there were more than 5800 prescriptions written, an increase of 30% over the third quarter. Momentum continued building into the fourth quarter with a favorable ramp. *However, these results have yet to reflect the positive effect reimbursement will have for gammaCore, which largely started in this year. Reimbursement that includes individuals managed by CVS Caremark, Highmark, as well as the Federal Supply Schedule and more specifically the Veterans Administration and Department of Defense.*

Our reported fourth quarter 2018 GAAP revenue was \$368,000. We also dispensed approximately \$1.7 million worth of gammaCore prescriptions pursuant to ongoing promotional programs. These programs are designed for patients who do not yet have reimbursement, otherwise known as demand revenue. As such the potential demand product sales value of gammaCore prescriptions dispensed during the fourth quarter of 2018 was approximately \$2.1 million.

* * *

Strategically building out the sales team through 2020 with the capability to reach 10,000 target physicians. We noted this expansion on our third quarter call, and I'm pleased to say that we remain on track to achieve this goal.

* * *

Key to our ongoing growth is continued expansion of insurance coverage or reimbursement among commercial payers. We remain on track to achieve 75 million covered lives by the middle of this year and 100 million by the end of the year. We had an impressive quarter-over-quarter growth in covered lives over the past two quarters. From 33 million in Q3 with an additional 21 million in Q4 and 5 million more we just announced recently, adding up to the approximate 60 million covered lives that we currently have in the United States.

170. Vraniak commented on the voucher program and other promotional programs,

stating:

As Frank noted earlier, the majority of gammaCore prescriptions during the quarter were dispensed under promotional programs. As a result, we're proud to report that we've delivered an additional \$1.7 million of product sales value of gammaCore therapy to patients through our promotional programs.

This includes vouchers or free therapy and co-pay assistance. Through our co-pay assistance program, we assist patients who have obtained commercial coverage with up to \$100 of their co-pay at the time that gammaCore dispensed. *We continue to believe these programs are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapy to physicians who write prescriptions and promoting U.S. commercial payer coverage and coverage discussions as a result of patient and physician demand.*

171. An analyst from Evercore questioned the Company's cash burn and defendant Amato reassured investors that it was not an issue, stating:

Yes, I think you've hit the nail on the head. When Glenn references a \$4 million a month cash burn, that's an average burn for the year we expect. We've had that burn up until this point for the most part, that is outflows what Glenn is reporting on. So that's what our expenses are going to be. With respect to revenue that comes in to offset some of that burn, we do expect that to be sequential and accelerated through the year, as I mentioned on the call earlier.

So, when we have some of this reimbursement that will come through for CVS Caremark, Highmark, also the federal supply schedule and any new PBMs and/or commercial insurance plans that we're expecting this year, additional Blue Cross Blue Shield plans to be exact, that will offset to a great degree some of that burden.

I just want to add one other comment in here, and that is, although the burn will be on average monthly \$4 million, we'll have months where we'll pay bonuses to the sales force and to folks in headquarters, and that'll pop up here and there on a monthly basis. But on average, we expect a \$4 million outflow on expense or cash burn for the Company.

172. The statements in ¶¶ 168-171 above were materially false and/or misleading and failed to disclose material adverse facts. Among other things, the March 2019 Press Release and related earnings conference call failed to disclose to investors: (i) that gammaCore did not enjoy any advantages over other acute treatments for migraines and episodic cluster headaches and in fact was most often regarded as a supplemental treatment instead of a primary treatment; (ii) that gammaCore's voucher program was not effective in increasing adoption of gammaCore and in fact was negatively effecting reimbursement by payors, making it appear as if the device was more popular than it actually was, and increasing Company costs; (iii) that the Company's agreements

with payors had restrictions limiting the patient population the payors would cover; (iv) that there were numerous issues with payor formularies and diagnostic codes impeding payor reimbursement agreements; and (v) that the Company's business plan and strategy was unsustainable because electroCore lacked sufficient revenue to be profitable. *See also ¶ 179.*

173. On March 28, 2019, the Company filed its 2018 Form 10-K with the SEC, signed by defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra and Tullis, and affirming the information provided in the March 2019 Press Release. Defendants Amato and Vraniak also signed certifications, containing the same statements as in ¶ 161 pursuant to SOX.

174. In addition, the 2018 Form 10-K reiterated similar language as contained in the Registration Statement regarding electroCore's purported competitive advantages, stating:

Competitive Strengths

We believe the competitive strengths of our company and our novel and proprietary self-administered bioelectronic therapy include:

- ***Innovative bioelectronic medicine approach.*** Our gammaCore therapy uses a proprietary electric signal to safely deliver bioelectronic medicine, which causes targeted pharmacologic-like changes in neurotransmitter expression and in the immune system, without systemic exposure to exogenous chemicals, in a manner that has been shown to have minimal side effects through clinical studies encompassing thousands of patients (several of which are more fully described herein).
- ***Our non-invasive therapy unlocks the long-held potential of VNS.*** VNS therapy can, for the first time, be delivered safely and comfortably through the skin using gammaCore. This eliminates the need for costly, invasive surgery that requires the implantation of an expensive medical device. VNS therapy is no longer reserved for the most refractory patients, and is now a first-line treatment option.
- ***Commercializing our therapy through traditional pharmaceutical channels.*** Our monthly prescription model, made possible by our noninvasive delivery modality, empowers medical professionals to prescribe nVNS on a monthly basis through the same channel they would prescribe any other specialty medication. Our RFID refill card enables us to offer nVNS therapy on a monthly basis, at the price of a branded pharmaceutical, which is typical of a traditional drug reimbursement model

managed by pharmacy benefit managers and other commercial payers. Beginning in the first quarter of 2019, we have agreements with commercial payers and the Federal Supply Schedule (Veterans Administration and Department of Defense) that we estimate provide reimbursement of gammaCore for approximately 53 million lives. Although there can be no assurance of success, we continue discussions with additional payers and PBMs regarding up to an additional 90 million lives in the United States with a goal of securing reimbursement for an aggregate of 75 million lives in the United States by the beginning of the third quarter of 2019, and an aggregate of 100 million lives in the United States by the end of 2019.

- ***Highly scalable and low investment manufacturing with digital refills.*** Our low manufacturing and assembly costs allow us to scale to meet demand with minimal additional investment. With the launch of the gammaCore Sapphire, which uses RFID cards for refills, our gross margins are expected to increase significantly. When the payers are in place, we have the capability to integrate our onboard Bluetooth technology with the payer systems to leverage a cloud-based refill delivery process, which we believe will enable greater efficiencies, further enhancing our gross margins.
- ***Potential for rapid label expansion in headache and regulatory approval in additional indications.*** The safety profile of gammaCore enabled us to utilize the *de novo* regulatory pathway through which the FDA established a new therapeutic category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). Through the 510(k) pathway, we received clearance for our gammaCore therapy for the acute treatment of pain associated with migraine in adults in January 2018, and clearance for the prevention of cluster headaches in December 2018. We believe a similar regulatory pathway may be available to us for additional indications in headache, including the prevention of migraine, the expansion of our label to include adolescents, and the treatment of post-traumatic headaches. We also anticipate seeking regulatory authorization to commercialize our therapy in rheumatological conditions through similar pathways.

* * *

- ***Highly experienced management team.*** Our management team includes a diverse group of executives with significant experience in senior positions in the pharmaceutical and medical device industries, including positions at Pfizer, Merck, Novartis, Stryker and Zimmer Biomet. Members of our team have been involved in the launch and marketing of products including Motrin, Celebrex, and the migraine drugs Axert and Maxalt. Our team's pharmaceutical experience in clinical development, sales, marketing and reimbursement, and its medical device experience in research, development and regulatory affairs, allow us to pursue our strategy and growth plans.

175. The 2018 10-K also included information on electroCore's market sizes and scope similar to its statements in the Registration Statement (*see ¶¶ 112-113*), and the purported lack of satisfactory treatments, stating, in relevant part:

Current Acute Migraine Treatments and Their Limitations. Triptan medications, or Triptans, are a family of tryptamine-based drugs first sold in the 1990s, which account for approximately 80% of the acute treatments prescribed for migraine. Triptans are sold in oral, nasal, and subcutaneous formulations. Through their binding to specific serotonin receptor subgroups, Triptans cause constriction of blood vessels in the outer covering of the brain, or the meninges. This vasoconstrictive activity may also affect blood vessels in other areas of the body, including the heart, which accounts for important risks associated with their use, and labeling limitations on the frequency of their use.

Other less commonly prescribed acute migraine treatments include ergotamines and analgesics, including non-steroidal anti-inflammatory drugs, or NSAIDs, acetaminophen and antiemetics. Dihydroergotamine, or DHE, is a grain fungus derivative that, like triptans, is a potent vasoconstrictor. DHE has been used for more than 50 years for the treatment of migraine, but modern physicians rarely prescribe it because of significant side effects. More specifically, ergotamines and triptans are both vasoconstrictors with labels citing the risk of their use in migraine sufferers with risk factors for cardiovascular disease. Opioids are often dispensed for migraine attacks in emergency departments; however, in the treatment guidelines referenced by the National Institutes of Health, their use is not recommended for the acute treatment of migraine. Opioid use for migraine is associated with increased disability and health care utilization. The U.S. Centers for Disease Control and Prevention has recognized the growing issue of opioid misuse, abuse and addiction and officially classified prescription opioid abuse as an epidemic. Data from a 2009 study conducted by the American Migraine Prevalence and Prevention Study suggests that about 16% of migraine patients are current opioid users and 16% of those patients are likely dependent. Although there are more prescription therapies available for migraineurs than CH sufferers, according to the U.S. Pharmacist, a leading pharmacy publication, upwards of 60% of the migraine patient population has reported dissatisfaction with, or has contraindications to, the current standard of care treatments for migraine. These medications include triptans, ergotamines and anti-epileptic medications. Despite the fact that neurologists recognize the limited efficacy of, and the potential for abuse associated with, opioids, they continue to be prescribed at high rates, particularly in emergency departments for the treatment of migraine. Many other primary headache conditions, and secondary headaches, such as post-traumatic headache, have proven refractory to pharmaceutical interventions, presenting a significant unmet need in the market.

* * *

Migraine Prophylaxis Market

According to the U.S. Agency for Healthcare Research and Quality, only about 12% of adults with high frequency or chronic migraine take preventive medications. According to the American Migraine Foundation, medication side effects often limit the use of migraine medications.

Currently Used Therapies for Migraine Prevention and Their Limitations. Prior to the approval of CGRP antibodies by the FDA, there were five products approved by the FDA for the prevention of migraine: anti-epileptic drugs, topiramate (Topamax) and valproic acid (Depakote), beta-blockers, propranolol (Inderal) and timolol (Blocadren), and BOTOX. BOTOX is the only product that has been approved by the FDA for the prevention of chronic migraine, and its label is limited to that subgroup. In all cases, these medications were first approved for other uses.

These current treatments are ineffective or inconvenient for some patients, and their use has been limited by issues with tolerability and side effects, including cognitive impairment, nausea, fatigue and sleep disturbance. Anti-epileptic drugs are also associated with poor pregnancy outcomes and fetal abnormalities, which is a concern for women of childbearing years. In clinical trials, these medications require four to six weeks of daily administration before most patients experience measurable clinical benefit. For example, BOTOX requires approximately 31 subcutaneous injections at various sites on the head and neck, repeated every 12 weeks. There are currently three antibodies to CGRP and its receptor approved by FDA for the prevention of migraine by Teva Pharmaceutical Industries Ltd., and Eli Lilly and Company, and by Amgen Inc., which is in a co-marketing partnership with Novartis International AG, approved by the FDA in May 2018. There are a number of medical devices that have been marketed for the treatment of migraine, including Cefaly and the Spring TMS device.

We believe there is a need for a new therapy that can either prevent migraines or reduce their severity to a level at which supplemental existing abortive therapies can provide relief as needed, with reduced side effects. Such a therapy could provide benefit for both patients on existing therapies and patients who have abandoned therapy.

176. The Company highlighted electroCore's regulatory clearances, recent studies, and intent to seek greater label expansion with the FDA, stating, in relevant part:

Migraine Prevention

As previously described, the grant by FDA of our *de novo* submission resulted in a new Class II regulatory category: External Vagus Nerve Stimulator for Headache (21 CFR 882-5892). The establishment of this product category permits us to apply for label expansions through the 510(k) regulatory pathway utilizing our own product as the predicate. With the recent clearance of our label expansion to CH, it

is now our intention to seek the expansion of our label for the prevention of migraine. As described below, we have conducted, and continue to conduct clinical studies to support this indication.

177. The 2018 Form 10-K also discussed electroCore's key strategies in becoming a market leader which were the same or substantially similar to those discussed in the Registration Statement (¶ 114).

178. Additionally, the 2018 Form 10-K discussed the Company's commercialization processes and purported successes, stating, in relevant part:

As of January 2019, we have agreements or arrangements with commercial payers, one pharmacy benefit manager, or PBM and the Federal Supply Schedule, or FSS, that we estimate provide for reimbursement for gammaCore as either a pharmacy benefit or medical benefit for approximately 53 million lives in the United States. Although there can be no assurance of success, our payer access team is negotiating contracts with several additional insurance plans and PBMs covering an additional approximately 90 million commercial lives, and in clinical review with plans covering an additional approximately 50 million lives.

* * *

Strategy and Implementation

Our commercial strategy has been focused on the following priorities:

- ***Drive advocacy of gammaCore as a leading headache therapy.*** Our advocacy strategy has been to establish gammaCore as a preferred treatment option in CH, and expand from that position into migraine. The core of this strategy is our physician outreach, professional education, peer reviewed publications, and participation in national and global professional society meetings.

* * *

- ***Drive reimbursement of our therapy.*** Our strategy to secure reimbursement for gammaCore therapy across the majority of CH and migraine patients began 18 months prior to market entry, in early 2016, when we initiated pipeline presentations across the largest two-dozen commercial payers in the United States. Based on the gammaCore monthly prescription model, many payers indicated that we should advocate for reimbursement as a pharmacy benefit, especially among the pharmacy benefit management, or PBM, companies. It is typical for reimbursement from PBMs to come by way of rebate agreements, requiring the company to offer significant

discounts, in the form of rebate payments, in return for gaining access to the PBM's population of potential patients. Preferred positioning within the PBM's system, which typically entails the product having the fewest restrictions and the lowest patient co-pay amounts, generally is provided to the companies providing the deepest discounts. It has been our strategy to identify the necessary rebate levels to gain the appropriate access. In addition, we are providing co-pay assistance to minimize the financial burden placed on the patient for filling the prescription. While we have been successful in negotiating several coverage agreements, and are currently in ongoing pharmacy benefit coverage negotiations with other payers, we have encountered some other payers, including the Federal government, who prefer to provide coverage for our therapy as a medical benefit. For these payers, negotiating reimbursement for gammaCore requires a different approach, in which the rebates are smaller or in some cases non-existent, and our support of the patient's co-pay may need to be significantly higher, as medical benefit deductibles are typically much higher than those for pharmacy products.

In 2018, our strategy focused on engaging, negotiating and securing agreements with the commercial payers and the components of the Federal government programs covering men and women aged 18 to 55, as these payers cover approximately 92% of patients experiencing migraines and cluster headaches. Payers in the United States typically make coverage and reimbursement decisions with respect to new therapies based on three key factors: the strength of the therapy's clinical data; observed patient demand; and the absolute and relative costs of the therapy.

* * *

- ***Build a leading commercial presence.*** To establish a leading commercial presence, we adopted a four-part strategy comprised of: identifying the leading prescribing physicians providing secondary care to complex headache patients; engaging experienced sales specialists with deep knowledge of the target space and the physician community with whom they will be engaged; implementing a distribution platform and specialty hub supporting all aspects of the physician-patient-payer relationship, and creating a marketing engagement program to ensure that patients and physicians are aware of the value proposition of gammaCore.

179. The above statements in ¶¶ 173-78 were materially false and/or misleading and/or failed to disclose that:

- gammaCore did not enjoy any competitive advantages over other treatments for eCH and migraines. At the same time gammaCore was entering the market, several

other similar medical devices also had entered or were entering the market with several already approved for both acute and preventative treatment and “comparable [in effectiveness].” In addition, a new category of drugs had already, or were just about to, receive FDA approval at the time of electroCore’s IPO. These CGRP drugs, including Aimovig, which was specifically designed for migraine prevention, the larger market electroCore planned to pursue, was not only regarded as more effective than gammaCore, but was covered by insurance, a key prohibitive issue physicians had with gammaCore. Although facing these competitors, the Exchange Act Defendants barely mentioned such competition and nowhere discussed the competitive advantages certain of those drugs had over gammaCore in being covered by insurers and the increasing pricing pressure the introduction of these products was causing the Company.

- (ii) Relatedly, the Exchange Act Defendants failed to disclose the fact that gammaCore was most often regarded as a supplemental treatment instead of a primary treatment for migraine. Cantor Fitzgerald pointed this out in several reports, stating in its initiating report that the “Company [is] planning to target [gammaCore] as a adjunctive treatment early on (for combinations with CGRPs, botox, and other current treatments) . . .” and in an October 22, 2018 report stated “[w]e see the biggest potential in adjunctive therapy alongside current and emerging treatments including CGRP mAbs.” Defendant Amato was even forced to admit during the Company’s first quarter 2019 earnings call that CVS would only cover gammaCore if a “patient has failed at least three other prescribed medications.” Thus, gammaCore was not a primary treatment as portrayed.

- (iii) The Exchange Act Defendants failed to disclose and/or misrepresented numerous key aspects of the Company's purported "business strategy" and "commercialization" of gammaCore.
- (a) *First*, the Exchange Act Defendants misrepresented the Company's relationships with insurance companies and commercial payors claiming, *inter alia*, to have "agreements" and access to reimbursement for millions of patients. In reality, electroCore's agreements were limited, with, for example, CVS not including gammaCore on CVS's template formulary and requiring patients to have tried and had no success with three other treatments before gammaCore.
- (b) *Second*, electroCore was having a multitude of other issues in obtaining insurance coverage, but failed to disclose any of the issues. For example, as explained in ¶¶ 77-78, there were issues with eligibility for certain diagnostic codes which made it more difficult to reach agreements with commercial payors. In fact, defendant Amato admitted during the first quarter 2019 earnings call that a standard that "universalizes our codes for inclusion in all pharmacopoeia" was not developed until 2019 and that First Databank, the largest database used by commercial payors, did not agree to "build[] a third database which [would] include all codes for [gammaCore]" until 2019 and that it would not be available until 2020.
- (c) *Third*, as a result of the above issues and the Company's attempts to promote gammaCore as both a durable medical device and a pharmacy benefit, physicians were reticent to prescribe gammaCore because

reimbursement was hard to obtain and took additional steps that only about 10% of doctors were willing to undertake. The increased burdens on physicians also increased expenses for electroCore as the Company's personnel had to spend substantial time assisting physicians with the paperwork and following up on coverage.

- (d) *Fourth*, the Exchange Act Defendants failed to disclose that electroCore was dependent on its voucher program and other promotional programs to grow sales, and that not only was the voucher program failing to increase revenues and increasing losses, it was substantially impeding the Company's progress with payors. Specifically, the voucher program bypassed the insurance company so potential payors never saw the demonstrated demand for gammaCore, ultimately making it less likely for them to agree to coverage.
- (iv) The Exchange Act Defendants further failed to disclose that all of the above would require significant cash outlays, accelerating cash burn and making the purported business strategies unsustainable.
- (v) The Exchange Act Defendants also misrepresented the sufficiency of electroCore's clinical data demonstrating that gammaCore was effective and safe for migraine prevention and that as a result, the Company's 510(k) submission for the use of gammaCore for migraine prevention was unlikely to be approved by the FDA in the near future. As CW5 noted, the FDA had raised concerns about the robustness of electroCore's data to support the use of gammaCore for migraine prevention prior to August 2019.

(vi) As a result of the forgoing, the Exchange Act Defendants' positive statements about Company's business, operations, and prospects, were materially misleading and/or lacked a reasonable basis.

B. The Truth Is Slowly Revealed

180. On May 14, 2019, electroCore issued a press release, also filed with the SEC as Exhibit 99.1 to a Form 8-K signed by defendant Posner, titled "electroCore Announces First Quarter 2019 Financial Results" (the "May 2019 Press Release"). The May 2019 Press Release stated, in relevant part:

First Quarter 2019 and Recent Highlights

- Nearly 2,200 prescribing physicians through the first quarter of 2019, up from approximately 1,800 in the fourth quarter of 2018
- Total prescriptions written were approximately 6,100 in the first quarter of 2019 compared to 5,800 in the fourth quarter of 2018
- Prescriptions dispensed were approximately 3,000 in the first quarter of 2019, relatively unchanged from the fourth quarter of 2018

* * *

"Our first quarter 2019 operating results are only beginning to reflect the positive steps that we took during the second half of last year," said Frank Amato, chief executive officer of electroCore. "Notably, *our first quarter results do not fully reflect the positive impact of new payers that were implemented during the quarter, including CVS Caremark, Highmark, and the Veteran's Administration or Partners for Coverage, our expanded free goods program. We are establishing a new approach to headache therapy and recognize that our growth will be gated by the realities of carving a new market position in a lucrative but crowded therapeutic segment. gammaCore Sapphire has a unique position as the only non-invasive vagus nerve stimulation device approved by FDA to treat both migraine and cluster headache, and the only therapy of any type approved for the prevention of cluster headache.* We are working with payers to help them decide how to pay for a product that can be reimbursed through multiple pathways. We are pleased by our accomplishments to date and believe our market penetration will increase as the awareness of our therapy expands and when we add further payer coverage."

First Quarter 2019 Financial Results

For the quarter ended March 31, 2019, electroCore reported net sales of \$410,000, as compared to \$81,000 in the first quarter of 2018 and \$368,000 in the fourth quarter of 2018. The increase in revenue reflects increased sales of gammaCore Sapphire.

Total operating expenses for first quarter of 2019 were \$14.5 million, as compared to \$9.1 million for the first quarter of 2018. The increase in operating expense was driven primarily by increased sales and marketing expenses, as well as an increase in stock-based compensation.

Operating loss for the first quarter of 2019 was \$14.2 million as compared to an operating loss of \$9.1 million in the first quarter of 2018.

Cash and cash equivalents and marketable securities at March 31, 2019 totaled \$52.4 million, as compared to \$68.6 million at December 31, 2018.

The net cash burn of \$16.2 million for the quarter ended March 31, 2019, included working capital uses of cash due to a \$1.6 million increase in inventory and approximately \$2.1 million of payments related to 2018 accrued compensation.

181. The disappointing earnings results, purported delay of positive results from new payors, and admission that the market was “crowded” did not reveal the full truth, and on the earnings conference call the same day, certain defendants continued to make materially false and misleading statements and omit material facts. On the call, defendant Amato again touted the “momentum” of gaining “patients, physicians, and payers,” while revealing the abysmal reimbursement numbers and extra onerous requirements under certain agreements, stating, in relevant part:

As you know in 2018, we took a number of key steps to build out our commercial infrastructure to support the launch of gammaCore. It positioned the Company for growth in 2019. Our quarter-over-quarter growth in total prescriptions, refilled prescriptions and prescribing physicians demonstrated that demand for our therapy was strong throughout 2018 and that the business model of delivering our therapy in monthly prescriptions is robust.

Toady [sic], I’m pleased to report that the first quarter of 2019 has continued that trend. We have sustained momentum among patients, physicians and payers. During the first quarter, we had key milestones across all the leading indicators of our business including total prescription with March coming in with our best monthly total to-date. This increase in prescriptions written is a result of writing by existing prescribers as well as newly prescribing physicians. At the end of 2018,

we reported that we have reached over 1,800 patients who had read at least one prescription.

By the end of Q1, we have seen prescriptions from 2,170 physicians cumulatively since the launch of product. 332 new physicians prescribed gammaCore from the first time in Q1, which speaks to the comfort that physicians have in prescribing a therapy that is safe and had minus systematic side effects no drug interactions. During the quarter, we expanded our free goods program Partners for Coverage our PFC, which was initiated in Q4. Under this program, our specialty pharmacy partner Asembia dispenses gammaCore or one month of therapy patients to qualify.

* * *

Shifting now from the free good program to the progress we've made in gaining the reimbursement, throughout the first quarter we began to see the anticipated increase in reimbursed prescriptions being processed to both CVS Caremark and the Federal Supply Schedule or FSS. In order to actualize the revenue potential of the FSS contract within the military channel, we spent and continued to spent [sic] a considerable amount of our effort working through distribution logistics to bring each hospital and military treatments facility online.

Each of the targeted 33 individual military treatment facilities and 80 Veterans Administration centers require an understanding of how its local distribution process works. To that end, our commercial team brought 20 military facilities on line that purchased product during the first quarter. Similarly, regarding patients covered by the three large PBM networks, CVS Caremark, Express Scripts and OptumRx, more than 5,000 prescriptions have been filed -- filled under the Partners for Coverage program, the prior voucher program or through patient self-pay.

The majority of these prescriptions await approval of the required prior authorization and represent potential reimbursement. We are starting to see the log jam break with a better than 250% increased from Q4 to Q1 in reimbursed prescriptions seen through the CVS Caremark agreement. We are still in the early days of the implementation of the CVS Caremark agreement. So, the increases are over a small but now growing base and we are encouraged by the trend. Importantly, the April numbers show a continuation of this growth.

With this in mind in the first quarter 2019, we were able to realize GAAP revenue of approximately \$410,000, about 11% growth over the fourth quarter. We also dispensed in the U.S. an additional 1.6 million worth of gammaCore prescriptions through the ongoing promotional programs, which include both our Partners for Coverage program and co-pay assistance.

In total, the potential demand product sales value of gammaCore prescriptions dispensed during the first quarter of 2019 was similar to what we reported to the fourth quarter of 2018 were approximately \$2 million. As more of these

promotional descriptions get reimbursed, we expect to see it reflected in GAAP revenue and will continue the revenue ramp that we are anticipating this year.

* * *

In the PBM channel, our agreement with CVS Caremark went into effect in January of this year. ***gammaCore is currently a non preferred branded product requiring a co-pay currently covered to our co-pay assistance that the prescription be written by a neurologist and the patient has failed at least three other prescribed medications.***

To date, over 1,600 CVS Caremark patients have been prescribed gammaCore. Nearly 1100 prior authorization requests have been sent to prescribing physicians for which 800 responses have been received in return. ***Because the paper work is not only still correctly we are working closely with neurologist to whole new ability to provide required information to CVS Caremark accurately.***

182. On the call, defendant Amato also admitted that a standard that “universalizes our codes for inclusion in all pharmacopoeia” was not developed until 2019 and that First Databank, the largest database used by commercial payors, did not agree to “build[] a third database which [would] include all the codes for [gammaCore]” until 2019.

183. Defendant Posner revealed that due to the “new coverage decision” that revenues would not be seen until later in 2019:

Due largely to the timing of new coverage decision, on the part of CVS Caremark, the Federal Supply schedule and others that commence reimbursement in the first quarter of 2019 as well as continued growth in unique prescribers and the ongoing conversion of promotional scripts to be reimbursed, we continue to anticipate that revenue for 2019 we'll be back-end weighted.

Specific to the second quarter for example, we have already seen a growth in the number of product requisitions from the VA and DoD facilities in April that was almost as much as all of the first quarter. Of course, the growth is over very small base, but it speaks to the multiple factors that are all converging on a growing opportunity.

184. On this news, electroCore's share price fell \$1.58 per share, or 29.64%, from a closing price per share of \$5.33 on May 14, 2019 to a closing price per share of \$3.75 on May 15, 2019.

185. On May 15, 2019, electroCore filed with the SEC its quarterly report on Form 10-Q for the quarter ended March 31, 2019 (the “1Q19 10-Q”), affirming the financial results as reported in the May 2019 Press Release. The 1Q19 10-Q was signed by defendants Amato and Posner and contained their signed certifications, containing the same statements as in ¶ 161 pursuant to SOX.

186. The 1Q19 10-Q once again highlighted the voucher program as a mechanism that purportedly permitted the Company to gain access to commercial payors:

In February 2018, we began a formal physician training program engaging key opinion leaders throughout the United States to highlight the clinical evidence and benefits of gammaCore for the acute treatment of pain associated with both migraine and episodic cluster headache and to train their colleagues on how to prescribe gammaCore. Concurrently, we began a program that provided these trained physicians with vouchers, which allowed them to provide new patients with a one-time 31-day prescription at no charge to the patient. This voucher program was implemented with three goals: to provide patients therapy at no charge; to demonstrate to physicians the benefits of gammaCore therapy; and to prompt U.S. commercial payers to provide pharmacy benefit coverage for the product as a result of their observation of patient demand for the therapy. This program has resulted in significant increases in prescriptions for gammaCore and has prompted negotiations with numerous commercial payers, resulting in non-preferred medical and pharmacy reimbursement in approximately 10 million lives and medical exception coverage for an additional 30 million pharmacy benefit lives in the first quarter of 2019.

187. Just over two weeks after announcing the disappointing first quarter 2019 results, on May 29, 2019, the Company issued a press release, also filed with the SEC as Exhibit 99.1 to a Form 8-K signed by defendant Posner, titled “electroCore Announces Comprehensive Redeployment and Cost Reduction Plan.” The press release stated, in relevant part:

electroCore, Inc. (Nasdaq: ECOR), a commercial-stage bioelectronic medicine company, today announced that ***management and the Board of Directors are making significant adjustments to the deployment of personnel and resources across the organization.*** The effort is intended to focus the Company on currently available and near-term revenue opportunities and on clinical programs specifically designed to expand the gammaCore™ product labeling. ***To achieve this goal the Company is right-sizing across its organization, including its field sales force and clinical operations.*** The Company will focus its

resources on high-value geographic and other sales territories where the current prescriber base and regional payer coverage are most concentrated including:

- i. Regional payers, some of whom have recently amended their policies to permit reimbursement for electroCore's principal offering, gammaCore™.
- ii. The Veterans Administration and Department of Defense, covered under the Federal Supply Schedule contract secured by the Company in December 2018.
- iii. The United Kingdom, where a recent Innovative Technology Program cluster headache treatment award offers the Company the potential to generate revenue.
- iv. Other potential revenue opportunities in the pain management field.

The Company will continue to pursue relationships with pharmacy benefit managers.

electroCore also announced that it is scaling back its clinical development program as part of the redeployment of resources. Changes include the postponement of several planned studies while focusing on opportunities to broaden the approved indications for gammaCore™ products. The Company is also reducing its medical affairs activities consistent with its revised commercial plan.

The broad-based redeployment and expense reduction plan will be fully implemented by the end of the second quarter of 2019. Beginning in the third quarter of 2019, the Company's average quarterly cash burn is expected to be less than \$7.0 million through 2020, compared to its previously reported expected burn of \$12.0 million per quarter. *Inclusive of one-time charges of approximately \$350,000 associated with implementation of this plan, the Company's second quarter cash burn is expected to be between \$11.0 million and \$11.5 million.* This expense reduction plan is further bolstered by the decision of the Company's independent directors to forgo all cash compensation for their Board service effective June 1, 2019, as well as the willingness of Frank Amato, the Company's chief executive officer, to voluntarily accept a 10% reduction in base annual cash compensation for the next 12 months, which is expected to be offset by a grant of restricted stock units valued at \$50,000 on June 7, 2019, the date of the Company's annual meeting of stockholders.

On March 31, 2019, the Company had \$52.4 million of cash, cash equivalents and marketable securities. Based on its current cash resources and cash flow projections, and after giving effect to the anticipated cost savings from the comprehensive redeployment and cost reduction plan, electroCore believes that it will have adequate resources to fund its operations into the beginning of 2021.

Mr. Frank Amato said, "Although we are cognizant of the pain and disappointment that may be experienced by those employees who will be separating from the Company as we reduce our workforce from 91 to 55 positions under this program, *the Board and management believe the adjustments to the expenditure of our resources are necessary as we respond to evolving market forces in the headache field.* As was shared on our most

recent earnings call, there are several promising commercial channels capable of providing significant sales acceleration.

188. On this news, electroCore's share price fell \$0.11, or over 5%, to close at \$1.95 per share on May 30, 2019, and continued to drop over the next two trading days, closing at \$1.65 per share on June 3, 2019.

189. On August 13, 2019, the Company issued a press release, attached as Exhibit 99.1 to a Form 8-K filed with the SEC, titled "electroCore Announces Second Quarter 2019 Financial Results" (the "August 2019 Press Release"). The August 2019 Press Release stated, in relevant part:

Second Quarter 2019 and Recent Highlights

* * *

- 510(k) premarket notification submission for migraine prevention accepted by FDA

* * *

"The comprehensive redeployment and cost reduction plan that we announced in May has made electroCore a more efficient organization capable of quickly reacting to changes in the rapidly evolving headache market. We believe our sharpened focus on our existing or near-term revenue generating opportunities is prudent **while we continue to work to add the support of larger payers, which can take some time to bring across the finish line.** We believe our non-invasive vagus nerve stimulation technology has applicability across a broad range of high-value indications, and we expect that we will be able to sustain or accelerate our current growth trajectory," Mr. Amato concluded.

Migraine Prevention Label Expansion Update

In July 2019, the FDA accepted for review electroCore's 510(k) premarket notification for a new indication for use of gammaCore for the prevention of migraine. Accordingly, the company continues to enroll subjects in the Premium 2 clinical trial to support the label expansion into migraine prevention, and to support the commercialization of gammaCore as a migraine prevention therapy should the indication receive FDA clearance. The company expects to receive the FDA's decision by the end of 2019 and to complete enrollment in Premium 2 in the first half of 2020.

Second Quarter 2019 Financial Results

For the quarter ended June 30, 2019, electroCore reported net sales of approximately \$623,000, as compared to approximately \$410,000 in the first quarter of 2019. The increase in revenue reflects increased sales in the United States and the United Kingdom.

Total operating expenses for second quarter of 2019 were approximately \$12.7 million, as compared to approximately \$16.4 million for the second quarter of 2018. The decrease was due primarily to a reduction in SG&A expense, which declined to approximately \$9.4 million in the second quarter 2019 from approximately \$12.0 million for the comparable period in 2018, primarily driven by a reduction in both marketing related costs and stock compensation expense. ***The current quarter included restructuring charges of approximately \$850,000 in connection with the comprehensive deployment and cost reduction plan announced in May.***

Operating loss for the second quarter of 2019 was \$12.4 million as compared to an operating loss of \$16.2 million in the second quarter of 2018.

Cash and cash equivalents and marketable securities at June 30, 2019 totaled approximately \$41.1 million, as compared to approximately \$68.6 million at December 31, 2018. Net cash burn for the quarter ended June 30, 2019 was approximately \$11.2 million, consistent with the previously stated expectation included in the Company's May press release announcing the comprehensive redeployment and cost reduction plan. Net cash burn for the quarter ended March 31, 2019 was approximately \$16.2 million.

As previously disclosed, beginning with the third quarter of 2019, the Company anticipates that its average quarterly cash burn will be less than \$7 million at least through 2020. ***electroCore anticipates that its cash burn for some quarters may exceed \$7 million due to working capital adjustments and one-time payments.*** Based on its current cash resources, and revenue and expense forecasts, electroCore believes that it will have adequate resources to fund its operations into the beginning of 2021.

190. An earnings conference call was also held on August 13, 2019. During this call, defendant Amato reiterated the key points from the August 2019 Press Release and further discussed the restrictions with the CVS agreement:

So, the gating factor for us remains getting rebate contracts in place with PBMs and also with local payers through, right now, Prime Therapeutics as the PBM for about half of those Blue's lives that I mentioned earlier. ***The CVS Caremark agreement we have in place still requires physicians to fill our paperwork, and prioritize for a majority of the patients within that plan, not all of them. We have offered contract with CVS Caremark and have been gone back and forth with our contract -- in various terms we've offered.***

So once that gets completed and is loaded that will likely get us access to a large majority of those folks without having to have paperwork filled out by the physician. It still might be a prior off, but it's electronic in the way it's dispensed to the physician today. And then with respect to the other plans, we have Express Scripts, Prime Therapeutics, and other plans in the United States that we're currently negotiating with.

In addition to that, we are *following-up on legislation that was published on opioids last year, which state directly that neuromodulation therapies could be a good alternative to opioids in the marketplace and CMS is looking at technologies, like ours, to code that in a way that patients will get access to the therapy without having to go through the traditional durable medical equipment pathway that most of these CMS improvements naturally follow.*

191. On this news, electroCore's share price fell \$0.17 per share, or over 10%, from a closing price per share of \$1.56 on August 13, 2019 to a closing price per share of \$1.39 on August 14, 2019.

192. Although according to CW5, electroCore knew by August 2019 (if not earlier) that the FDA had concerns about the robustness of electroCore's data supporting the use of gammaCore for migraine prevention, the Exchange Act Defendants did not reveal such knowledge until forced to do so. On September 25, 2019, the Company revealed that the FDA had requested more information and analysis of clinical data for electroCore's 510(k) submission, which the Company had submitted in order to expand the use of gammaCore. The press release stated, in relevant part:

electroCore, Inc. (Nasdaq: ECOR, or the "Company"), a commercial-stage bioelectronic medicine company, today announced that the U.S. Food and Drug Administration ("FDA") has requested more information and analysis of the clinical data included in the Company's premarket notification, or "510(k)" submission, seeking an expanded indication for the use of gammaCore™ (non-invasive vagus nerve stimulator). Although the Company has 180 days to respond to FDA's request, the Company expects to meet with the FDA in the fourth quarter to discuss the information request. gammaCore™ is currently FDA-cleared for the treatment of pain associated with episodic cluster headache and migraine headache, and adjunctive use for the prevention of cluster headache.

The data submitted in the 510(k) include the results of the Premium 1 study, a randomized, double-blind, sham-controlled trial of gammaCore™

"We look forward to meeting soon with the FDA to discuss our 510(k) submission and are committed to working with the agency to address their questions as quickly

as possible,” said Tony Fiorino, Chief Medical Officer of electroCore. “Meanwhile we continue to recruit subjects into the Premium 2 study which we anticipate will further define the clinical utility of gammaCore™ in the migraine space.”

193. On this news, the Company’s share price fell \$0.79, over 23%, to close at \$2.57 per share on September 25, 2019, on unusually heavy trading volume.

C. Additional Scienter Allegations

194. As alleged herein, each of the Exchange Act Defendants acted with scienter in that they knowingly or recklessly disregarded that the information disseminated to the public contained materially false and/or misleading information and omitted material information. Throughout the Class Period, the Exchange Act Defendants acted intentionally or in such a deliberately reckless manner as to constitute a fraud upon Lead Plaintiff and the Class. Such actions caused the price of electroCore securities to be artificially inflated.

195. In their respective roles as officers and/or directors of electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis were able to, and did, control the information disseminated to the investing public in the Company’s various SEC filings, press releases, and other public statements during the Class Period. As a result, each had the opportunity to falsify the information provided to the public regarding electroCore’s business and performance.

1. electroCore’s \$77.7 Million IPO

196. The Exchange Act Defendants’ fraudulent scheme and materially false and misleading statements and omissions ensured the success of the Company’s entry into the public equity markets. As stated above at ¶¶ 109-120, the Registration Statement was materially false and/or misleading and failed to disclose material adverse facts.

197. The Exchange Act Defendants’ materially false and misleading statements and omissions allowed electroCore to sell 5.98 million shares of common stock at \$15.00 per share

during its IPO, garnering net proceeds of more than \$77 million, cash electroCore needed to continue to operate with only \$1.5 million in cash and cash equivalents as of March 31, 2018.

2. Admitted Knowledge and Core Operations

198. electroCore was (and still is) an extremely small company with only 64 employees at the time of the IPO, increasing to 91 employees in early 2019 and then reducing the number of employees to 51 in May 2019. J. Errico and T. Errico founded the Company in 2005; Amato and Vraniak had been with the Company since 2012 and 2016, respectively; and Colucci, Moody, and Tullis had served as directors for at least a year prior to the IPO, if not more.

199. electroCore's Registration Statement and 2018 Form 10-K both touted the Company's “[h]ighly experienced management team” and listed it as a “competitive advantage”:

Our management team includes a diverse group of executives with significant experience in senior positions in the pharmaceutical and medical device industries, including positions at Pfizer Inc, Merck & Co., Novartis International AG, Stryker Corporation and Zimmer Biomet. Members of our team have been involved in the launch and marketing of products including Motrin, Celebrex, and the migraine drugs Axert and Maxalt. Our team's pharmaceutical experience in clinical development, sales, marketing and reimbursement, and its medical device experience in research, development and regulatory affairs, allow us to pursue our strategy and growth plans.

200. Amato, Vraniak, Posner, and J. Errico repeatedly admitted to having knowledge of electroCore's business through their public statements. For example:

- So where are we with the commercial payers and PBMs? *Currently we have multiple reimbursement agreements in place. The first of which is the CVS Caremark agreement, which will go into effect on January 1, 2019. Under this agreement, we have been advised that approximately 30 million of the 65 million U.S. individuals managed by CVS Caremark will have access to our therapy as a Tier 3 product beginning in January of 2019.* Potential access to the remaining 35 million lives will be gained through continuing negotiations with the payers within the CVS network. *Amato, Third Quarter 2018 Earnings Conference Call.*
- As Frank noted earlier, the majority of gammaCore prescriptions during the quarter were dispensed under promotional programs. As a result, we're proud

to report that we've delivered an additional \$1.7 million of product sales value of gammaCore therapy to patients through our promotional programs. ... This includes vouchers or free therapy and co-pay assistance. Through our co-pay assistance program, we assist patients who have obtained commercial coverage with up to \$100 of their co-pay at the time that gammaCore dispensed. We continue to believe these programs are accomplishing our objectives of providing patient therapy at no charge, demonstrating the benefits of gammaCore therapy to physicians who write prescriptions and promoting U.S. commercial payer coverage and coverage discussions as a result of patient and physician demand. *Vraniak, Fourth Quarter 2018 Earnings Conference Call.*

- Due largely to the timing of new coverage decision, on the part of CVS Caremark, the Federal Supply schedule and others that commence reimbursement in the first quarter of 2019 as well as continued growth in unique prescribers and the ongoing conversion of promotional scripts to be reimbursed, we continue to anticipate that revenue for 2019 we'll be back-end weighted. *Posner, First Quarter 2019 Earnings Conference Call.*
- As we've shared before, medical researchers the world over are busy studying vagus nerve stimulation for a variety of elements. This interest is the result of the ever growing body of scientific research demonstrating the potent effects of VNS, neurotransmitters, inflammatory mediators, metabolic signaling proteins and even on clotting factors. Translating this potential into the clinic and into commercial success ultimately requires payer reimbursement approval. And payers demand evidence based clinical presentations supported by peer reviewed publications. Fortunately, published clinical data is the cornerstone of our payer outreach efforts and in furtherance of this, I'd like to highlight one paper we recently announced that was published in the highly regarded Journal of the Headache and Pain, which is a retrospective study of chronic and episodic cluster patients who were using gammaCore for at least three to six months. ... On the clinical front, we are working hard to follow up our third label claim, which we received this past year for the prevention of cluster headache. With the clinical data to getting clearance for the potential label claim for the prevention of migraines. To this end, we are in ongoing discussions with FDA around an application that we plan to submit to support this label. Providing additional support for that indication will be our PREMIUM II trial, which is designed to extend the findings from our prior PREMIUM I trial. It will enroll up to 500 patients in 35 sites across the United States and it began enrollment in the fourth quarter of last year. ... Yes, Marie, this is J.P. The answer to that question is at the present time, it appears to be around 30% to 35%, but it's growing and it's growing rather significantly. We believe that the reason for that is because as the payers come online, the cost or outlay that the patient has to take on in order to remain on therapy is reduced. And so as a result, we saw 300% increases, as Frank mentioned, quarter-over-quarter from third to fourth quarter in refills and we expect and anticipate that to continue to grow into the first quarter and so, I would caution taking anything that I'm saying right now

as what it's going to be going forward, because these numbers continue to grow.
J. Errico, Fourth Quarter 2018 Earnings Conference Call.

201. Further, Amato, Vraniak, and Posner signed the SOX certifications for the Forms 10-K and 10-Q filed during the Class Period attesting that the information contained in the 2018 Form 10-K "fairly presents, in all material respects, the financial condition and results of operations of the Company."

202. By virtue of their executive and/or directorship positions within a small Company, where gammaCore was the flagship product and source of income, and the admitted knowledge above, the Exchange Act Defendants knew, or were reckless in not knowing, non-public material facts concerning gammaCore.

3. Internal Meetings and Reports

203. As discussed in ¶¶ 67, 72, 90, 93 above, the Individual Defendants had access to certain reports and/or were involved in either regular Company meetings or one-on-one meetings where they were updated on crucial information indicating that the statements made herein were materially false and/or misleading and omitted material facts. For example, CW3 provided regular updates to defendant Amato regarding CW3's efforts with commercial payors. CW3 also discussed the code eligibility issue with Amato during in-person meetings. CW5 stated that there were senior manager meetings twice a month where the Company's efforts to reach agreements with insurance companies were discussed. And, there were quarterly national sales conference calls led by Duhart who reported to Amato according to CW6. The Individual Defendants were also updated during weekly meetings on clinical trials according to CW7.

204. In addition, CW5 stated that defendant Amato received updates from all functional groups at the Company, *i.e.*, Commercial, Sales, Clinical Supply/Device Supply, and Clinical Operations, during the senior manager meetings that took place twice a month in the conference

room on the second floor of the Basking Ridge building. CW5 attended those meetings prior to the May 2019 layoffs. According to CW5, Liebler also met weekly with Amato in Amato's office.

205. CW6 recalled that Asembia (electroCore's distributor) had a portal showing the number of vouchers submitted for gammaCore, the dates on which prescriptions were written, and status updates for coverage requests. Thus the Exchange Act Defendants would have had access to this information.

4. Insider Sales

206. While in possession of material, nonpublic information regarding gammaCore's insurance reimbursement issues, among other things, defendant J. Errico sold 100,000 shares of electroCore stock during the Class Period reaping net proceeds of \$566,634.04, as illustrated in the table below. J. Errico had not sold any shares of electroCore prior to his first Class Period sale on January 15, 2019. Thus, J. Errico was highly motivated to engage in the alleged fraudulent scheme and issue materially false and misleading statements and/or omit material facts in order to inflate electroCore's securities price and maximize individual profits.

Date	No. Shares Sold ²	Price Per Share	Proceeds
1/15/2019	22,349	\$4.90	\$109,510.10
1/16/2019	19,810	\$4.89	\$96,870.90
1/17/2019	7,841	\$4.84	\$69,314.44
4/01/2019	10,408	\$6.97	\$72,543.76
4/11/2019	13,723	\$5.49	\$75,339.27
4/12/2019	25,869	\$5.53	\$143,055.57
Total	100,000		\$566,634.04

207. Indeed, J. Errico's Class Period sales did not go unnoticed. On the May 14, 2019 first quarter 2019 earnings call, an analyst from Evercore ISI raised the issue of J. Errico's sales:

And then last question I have to ask because a few investors have expressed dismay over JP [Errico] initiating stocks don't plan at the time of the stock is so far below

² While the shares sold were pursuant to a 10b5-1 plan, the plan was entered into during the Class Period.

the IPO price. So perhaps, you can address why you felt that this prudent timing, considering the poor optics and why we shouldn't take that as a lack of confidence and the outlook for the Company at the current valuation?

D. Loss Causation

208. During the Class Period, as detailed herein, the Exchange Act Defendants engaged in a fraudulent scheme to deceive the market that artificially inflated the price of electroCore securities and operated as a fraud or deceit on Class Period purchasers of electroCore securities.

209. The Exchange Act Defendants' materially false and/or misleading statements and omissions concealed, *inter alia*, that electroCore was facing increasing competition and pricing pressure; gammaCore was not enjoying advantages over other treatments and in fact was not even considered a primary treatment; the Company was struggling with physician adoption of the treatment and insurance coverage for gammaCore leading to increasing cash outlays in the form of product discounts, long-term use of voucher programs, and additional sales personnel; all resulting in unsustainable cash burn and an inability to increase revenues. As detailed above, when the truth was revealed, the price of electroCore's securities declined significantly as the prior artificial inflation was removed from the Company's stock price.

210. As a result of their purchases of electroCore's securities during the Class Period, at artificially inflated prices, Lead Plaintiff and the Class suffered damages under the federal securities laws.

211. The artificial inflation created by the Exchange Act Defendants' misrepresentations and omissions was partially removed in a series of disclosures as follows:

- (i) On May 14, 2019, the Company announced dismissal earnings and stated, among other things, that (i) new payors, including CVS whom the Company purportedly already had an agreement with, were *instituted* during the first quarter of 2019; (ii) the CVS agreement would only cover gammaCore for

patients after they had tried three other medications; and (iii) a universal diagnostic code for gammaCore had only just been instituted. *See ¶¶ 180-183.* Following these disclosures, electroCore's share price declined by \$1.58 per share, over 29%, on heavier than usual trading volume, to close on May 15, 2019 at \$3.75 per share.

- (ii) On May 29, 2019, electroCore announced a comprehensive redeployment and cost reduction plan, including scaling back its clinical development program, one of the purported key business strategies for the Company as gammaCore's approved uses served only a small subset of the headache population. On this news, electroCore's share price fell \$0.11, or over 5%, to close at \$1.95 per share on May 30, 2019 on unusually heavy trading volume. electroCore's share price continued to drop over the next two trading days on heavier than usual trading volume to finally close at \$1.65 per share on June 3, 2019, an overall decrease of over 15%.
- (iii) On August 13, 2019, the Company disclosed restructuring charges associated with the comprehensive deployment and cost reduction plan and announced an expected quarterly cash burn of over \$7 million. In addition, further details on the lack of a normal payor agreement with CVS were revealed. Following these disclosures, electroCore's share price fell \$0.17 per share, or over 10%, on unusually heavy trading volume, from a closing

price per share of \$1.56 on August 13, 2019 to a closing price per share of \$1.39 on August 14, 2019.

- (iv) On September 25, 2019, it was revealed that the FDA had requested more information and analysis of clinical data for the Company's 510(k) submission for expansion of use for gammaCore. On this news, electroCore's share price fell \$0.79 per share, or 23%, on unusually heavy trading volume, to close at \$2.57 per share on September 25, 2019.

212. The timing and magnitude of the price decline in electroCore's stock on the date of each disclosure above negates any inference that the losses suffered by Lead Plaintiff and the Class were caused by changed market conditions, macroeconomic or industry facts, or Company-specific facts unrelated to the Exchange Act Defendants' fraudulent conduct.

213. The damages suffered by Lead Plaintiff and the Class were the direct and proximate result of the Exchange Act Defendants' materially false and misleading statements and omissions that artificially inflated the Company's stock price and the subsequent significant decline in the value of the Company's stock when the truth concerning the Exchange Act Defendants' prior misrepresentations and fraudulent conduct were revealed.

E. No Safe Harbor

214. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false and/or misleading herein. The statements alleged herein all relate to then-existing facts and conditions.

215. To the extent that statements alleged to be false and/or misleading are characterized as forward-looking, the statutory safe harbor does not apply to such statements because they were not sufficiently identified as "forward-looking statements" when made, there were no meaningful

cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statements, and the Exchange Act Defendants had actual knowledge that the forward-looking statements were materially false or misleading at the time each such statement was made.

F. Presumption of Reliance; Fraud-on-the-Market

216. The market for electroCore securities was open, well-developed, and efficient at all relevant times. As a result of the Exchange Act Defendants' materially false and/or misleading statements and material omissions, electroCore securities traded at artificially inflated prices during the Class Period. Lead Plaintiff and the Class purchased or otherwise acquired the Company's securities relying on the integrity of the market price of such securities and on publicly available market information relating to electroCore, and have been damaged thereby.

217. During the Class Period, the artificial inflation of the value of electroCore's stock was caused by the material misrepresentations and omissions particularized in this Complaint, thereby causing the damages sustained by Lead Plaintiff and the Class. As described herein, during the Class Period, the Exchange Act Defendants made or caused to be made a series of materially false or misleading statements about the Company's business, prospects, and operations, causing the price of the Company's stock to be artificially inflated at all relevant times. When the truth was disclosed, it drove down the value of the Company's stock, causing Lead Plaintiff and other Class members that had purchased the stock at artificially inflated prices to be damaged as a result.

218. Lead Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- The Exchange Act Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- the omissions and misrepresentations were material;

- electroCore securities are traded in an efficient market;
- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
- the Company traded on the NASDAQ and was covered by analysts;
- the misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- Lead Plaintiff and members of the Class purchased, acquired, and/or sold electroCore securities between the time the Exchange Act Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

219. Based upon the foregoing, Lead Plaintiff and the Class are entitled to a presumption of reliance upon the integrity of the market.

220. Alternatively, Lead Plaintiff and the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as the Exchange Act Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

G. Causes of Action Under Sections 10(b) and 20(a) of the Exchange Act

COUNT IV

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 (Against All Exchange Act Defendants)

221. Lead Plaintiff repeats and re-alleges each and every allegation above as if fully set forth herein.

222. This Count is asserted against electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis for violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by the SEC.

223. During the Class Period, the Exchange Act Defendants carried out a plan, scheme, and course of conduct, which was intended to, and throughout the Class Period, did: (i) deceive

the investing public, including Lead Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of electroCore securities; and (iii) cause Lead Plaintiff and other members of the Class to purchase or otherwise acquire electroCore securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Exchange Act Defendants, and each of them, took the actions set forth herein.

224. The Exchange Act Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period in an effort to maintain artificially high market prices for electroCore's securities in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5 promulgated thereunder.

225. The Exchange Act Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal and misrepresent adverse material information about the Company's business, operations, and financial results, as specified herein.

226. Pursuant to the above plan, scheme, and course of conduct, each of the Exchange Act Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases, and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for electroCore securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented electroCore's true condition.

227. The Company and the Individual Defendants named in this Count had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Lead Plaintiff and the other members of the Class, or, in the alternative, the Exchange Act Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to these defendants. Said acts and omissions of the Exchange Act Defendants were committed willfully or with reckless disregard for the truth. In addition, each Exchange Act Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

228. Information showing that the Exchange Act Defendants acted knowingly or with reckless disregard for the truth is peculiarly within the Exchange Act Defendants' knowledge and control. As senior officers and directors of electroCore, the Individual Defendants named herein had knowledge of the details of electroCore's internal affairs.

229. The Individual Defendants named herein are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, these defendants were able to and did, directly or indirectly, control the content of the statements of electroCore. As senior officers and/or directors of a publicly-held company, the Individual Defendants named herein had a duty to disseminate timely, accurate, and truthful information with respect to electroCore's businesses, operations, financial condition, and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases, and public statements, the market price of electroCore securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning electroCore's business and financial condition which were concealed by the Exchange Act Defendants, Lead Plaintiff and the other

Class members purchased or otherwise acquired electroCore securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by the Exchange Act Defendants, and were damaged thereby.

230. During the Class Period, electroCore securities were traded on an active and efficient market. Lead Plaintiff and the Class, relying on the materially false and misleading statements described herein, which the Exchange Act Defendants made, issued, or caused to be disseminated, or relying upon the integrity of the market, purchased, or otherwise acquired shares of electroCore securities at prices artificially inflated by the Exchange Act Defendants' wrongful conduct. Had Lead Plaintiff and the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Lead Plaintiff and the Class, the true value of electroCore securities was substantially lower than the prices paid by Lead Plaintiff and the Class. The market price of electroCore securities declined sharply upon public disclosure of the facts alleged herein to the injury of Lead Plaintiff and the Class.

231. By reason of the conduct alleged herein, the Exchange Act Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and SEC Rule 10b-5.

232. As a direct and proximate result of the Exchange Act Defendants' wrongful conduct, Lead Plaintiff and the Class suffered damages in connection with their respective purchases, acquisitions, and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating material misrepresentations to the investing public.

COUNT V

**For Violations of Section 20(a) of the Exchange Act
(Against Amato, Vraniak, Posner, J. Errico, T. Errico,
Cox, Atieh, Colucci, Moody, Ondra, and Tullis)**

233. Lead Plaintiff repeats and re-alleges each and every allegation above as if fully set forth herein.

234. During the Class Period, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis participated in the operation and management of electroCore, and conducted and participated, directly and indirectly, in the conduct of electroCore's business affairs. Because of their senior positions and/or directorships, they knew the adverse non-public information about electroCore's misstatements regarding gammaCore and the Company's business.

235. As officers and/or directors of a publicly owned company, these defendants had a duty to disseminate accurate and truthful information with respect to electroCore and its flagship product, and to correct promptly any public statements issued by electroCore which had become materially false or misleading.

236. Because of their positions of control and authority as senior officers and/or directors, these defendants were able to and did control the contents of the various reports, press releases and public filings which electroCore disseminated in the marketplace during the Class Period. Throughout the Class Period, these defendants exercised their power and authority to cause electroCore to engage in the wrongful acts complained of herein. These Individual Defendants named herein, therefore, were "controlling persons" of electroCore within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of electroCore securities.

237. Each of the Individual Defendants named herein, therefore, acted as a controlling person of electroCore. By reason of their senior management positions and/or being directors of electroCore, each of these defendants had the power to direct the actions of, and exercised the same to cause, electroCore to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants named in this Count exercised control over the general operations of electroCore and possessed the power to control the specific activities which comprise the primary violations about which Lead Plaintiff and the other members of the Class complain.

238. By reason of the above conduct, the Individual Defendants named in this Count are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by electroCore.

VIII. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure and certifying Lead Plaintiff as the Class Representative;

B. Awarding compensatory damages in favor of Lead Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial;

C. Awarding Lead Plaintiff and the members of the Class rescission, disgorgement, and all other remedies in equity or in law pursuant to the Securities Act;

D. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

E. Awarding such other and further relief as this Court may deem just and proper.

IX. DEMAND FOR TRIAL BY JURY

Lead Plaintiff hereby demands a trial by jury.

Dated: July 17, 2020

Respectfully submitted,

BRAGAR EAGEL & SQUIRE, P.C.

/s/ Lawrence P. Eagel

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